Health Evidence Review Commission's Value-based Benefits Subcommittee

October 6, 2022

9:00 AM - 1:00 PM

Online Meeting

Join online meeting here

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Section 1.0

Call to Order

AGENDA
VALUE-BASED BENEFITS SUBCOMMITTEE
10/6/2022
9:00am - 1:00pm
Online meeting
All times are approximate

Note: Public testimony on specific agenda topics will be taken at the time that agenda item is discussed.

I. Call to Order, Roll Call, Approval of Minutes – Holly Jo Hodges **9:00 AM**

II. Staff report **9:05 AM**

III. Straightforward/Consent agenda **9:10 AM**

A. Consent table
B. Straightforward guideline note changes *(Routine changes that may be approved without discussion)*
C. COVID codes

IV. Advisory panel reports **9:15 AM**

A. **BHAP**

A. Residential therapy for anxiety *(Should therapy given in a residential setting be covered on the anxiety line?)*
B. Acupuncture guideline clarification for substance use disorder therapy *(Clarify when acupuncture treatment may be provided for people with substance use disorder)*
C. Somatization disorders *(Extreme anxiety about physical symptoms)*

V. Reports needing discussion **9:30 AM**

A. QALYs review *(Review how the Commission uses quality-adjusted life years in rare situations as context for decision-making)*

VI. Previous Discussion items **10:15 AM**

A. Inflammatory skin disease guideline modifications *(Guideline revision for conditions affecting skin)*

VII. New Discussion Items **10:30 AM**

A. Corneal collagen cross linkage for keratoconus (*Treatment for condition of the outer layer of the eye (cornea))*
B. Statement of intent for public health emergencies *(Clarify the Commission's intent for coverage of treatments and preventive services like vaccines when a public health emergency is declared)*

C. Solid organ transplant lines review *(General review of current coverage and guidelines in organs transplants other than bone marrow and cornea)*
D. Hydrocele repair in adults *(Consideration for coverage for adults for swelling or fluid collection in the scrotum)*
E. Below the line review *(Review of select conditions currently below the funding level)*
    A. Line 528 DEFORMITIES OF UPPER BODY AND ALL LIMBS
    B. Line 599 CONGENITAL DEFORMITIES OF KNEE
    C. Line 602 CONGENITAL ANOMALIES OF THE EAR WITHOUT IMPAIRMENT OF HEARING; UNILATERAL ANOMALIES
    D. Line 658 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
F. CPAP titration *(An overnight sleep study used to properly set continuous positive airway pressure (CPAP) therapy)*
G. Congenital foot deformity code review *(Foot conditions present since birth)*
H. Human growth hormone guideline *(Review coverage of a medication that can affect growth and other body functions)*
I. Chronic disease self-management programs *(Community self-management programs)*

VIII. Public comment **12:55 PM**

IX. Adjournment – Holly Jo Hodges **1:00 PM**

Value-based Benefits Subcommittee Recommendations Summary
For Presentation to:
Health Evidence Review Commission on August 11, 2022

For specific coding recommendations and guideline wording, please see the text of the 8/11/2022 VbBS minutes.

RECOMMENDED CODE MOVEMENT (changes to the 10/1/2022 Prioritized List unless otherwise noted)

- Add the procedure codes for adenoidectomy to the acute otitis media line
- Add the 2023 ICD-10-CM diagnosis codes to various lines and lists
- Add the diagnosis codes for conduct disorder and intermittent explosive disorder to a funded line (*effective 1/1/2023*)
- Add the diagnosis code for autoimmune encephalitis to a funded line (*effective 1/1/2023*)
- Add the procedure code for microsatellite instability testing to the funded colon cancer line
- Add the procedure code for canaloplasty to the funded line for glaucoma
- Add the procedure codes for high frequency chest wall oscillation devices to several funded lines *(effective 1/1/2023)*
- Make various straightforward coding changes

ITEMS CONSIDERED BUT NO RECOMMENDATIONS FOR CHANGES MADE

- Treatments for temporomandibular joint disorder (TMJ) were discussed but no reprioritization was recommended

RECOMMENDED GUIDELINE CHANGES (changes to the 10/1/2022 Prioritized List unless otherwise noted)

- Edit the guideline for ear tubes for recurrent acute otitis media to allow people with a greater range of developmental or high-risk conditions to have tubes without history of a specific number of infections
- Merge the guidelines regarding conduct disorder (*effective 1/1/2023*)
- Edit the PANDA/PANS guideline to clarify that autoimmune encephalitis is not included in the guideline restrictions (*effective 1/1/2023*)
- Edit the biomarkers for cancer guideline to indicate that microsatellite instability testing is now on the funded colon cancer line
- Edit the scoliosis guideline to remove an age limit for surgery and to include idiopathic adult scoliosis as an indication for surgery
- Add a new guideline for high frequency chest wall oscillation devices based on the new coverage guidance *(effective 1/1/2023)*
- Make various straightforward guideline note changes

2024 Biennial Review changes (changes to the 1/1/2024 Prioritized List)

- Delete the current unfunded conduct disorder line
- Move the insomnia diagnosis codes to a funded line with a new guideline restricting sedative-hypnotic medication use up to 1 month per year

VALUE-BASED BENEFITS SUBCOMMITTEE
Virtual Meeting
August 11, 2022
8:00 AM – 1:00 PM

Members Present: Kevin Olson, MD, Chair; Holly Jo Hodges, MD, MBA, Vice-chair; Kathryn Schabel, MD; Brian Duty, MD; Mike Collins; David Saenger, MD.

Members Absent: Adriane Irwin, PharmD; Cris Pinzon, MPH, BSN, BS, RN

Staff Present: Ariel Smits, MD, MPH; Amy Cantor, MD, MPH; Jason Gingerich; Liz Walker, PhD, MPH; Daphne Peck.

Also Attending: Dawn Mautner, MD & Diane Quiring (Oregon Health Authority); Val King, MD, MPH & Shauna Durbin, MPH (CEBP); Josiah Orina, MD (OHSU); Denis McCarthy, MD; Gary Hansen (Respirtech); Devin Fakner (Biotech); Peggy Kelley, MD (Providence); Amanda Trujillo; Carrie Woodman; Chris Ferrin; Chris Potters; Emily Rigler-Wright; Jasmine Reiber; Jessica Ickes; Joey Razzano; Laura Briggs; MEwald; PKP; Renee Doan; Siobhan Hess; smccarthy.

- **Roll Call/Minutes Approval/Staff Report**

  The meeting was called to order at 8:00 am and roll was called. A quorum of members was present at the meeting. Minutes from the 5/19/22 VbBS meeting were reviewed and approved.

  Smits reviewed the errata. Gingerich gave a staff report on ongoing waiver work within the agency. He also noted that the WPATH guidelines on the treatment of gender dysphoria had not yet been released. He also announced that future HERC and subcommittee meetings will continue to meet virtually given high transmission rates of COVID-19.

- **Topic: Straightforward/Consent Agenda**

Discussion: There was no discussion about the consent agenda items.

Recommended Actions:

1) Add 46615 (Anoscopy; with ablation of tumor(s), polyp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique) to line 157 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS
2) Add M50.121, M50.122, M50.123, and M50.13 (Cervical disc disorder with radiculopathy) to line 346 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS
3) Add 43266 (Esophagogastroduodenoscopy, flexible, transoral; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed)) to line 41 INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION
4) Add G96.198 (Other disorders of meninges, not elsewhere classified) to line 424 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
5) Add K80.20, K80.50, K80.70 (Calculus of gallbladder and/or bile duct) to line 55 COMPLICATED STONES OF THE GALLBLADDER AND BILE DUCTS; CHOLECYSTITIS
6) Add G56.1X family (Other lesions of median nerve) and G56.3X family (Lesion of radial nerve) to 416 PERIPHERAL NERVE ENTRAPMENT
    a. Remove G56.1X family and G56.3X family from lines 509 and 537 PERIPHERAL NERVE DISORDERS
7) Add CPT 96450 (Chemotherapy administration, into CNS (e.g., intrathecal), requiring and including spinal puncture) to line 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
8) Add K76.7 (Hepatorenal syndrome) to line 307 CIRRHOSIS OF LIVER OR BILIARY TRACT; BUDD-CHIARI SYNDROME; HEPATIC VEIN THROMBOSIS; INTRAHEPATIC VASCULAR MALFORMATIONS; CAROLI'S DISEASE Treatment: LIVER TRANSPLANT, LIVER-KIDNEY TRANSPLANT
9) Add the G61 (Inflammatory polyneuropathy) and G62 (Other and unspecified polyneuropathies) ICD-10-CM families to line 165 PREVENTIVE FOOT CARE IN HIGH-RISK PATIENTS
10) Advise HSD to add 90584 (Dengue vaccine, quadrivalent, live, 2 dose schedule, for subcutaneous use) to the Excluded File
11) Remove CPT 91110 (Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus through ileum, with interpretation and report) from lines 29 REGIONAL ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE and line 56 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE.
    a. Advise HSD to add CPT 91110 to the Diagnostic Procedures File
12) Modify GN9 as shown in appendix A
13) Modify GN3 as shown in appendix A
14) Add the following CPT codes to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS

0091A	Moderna Covid-19 vaccine administration – children ages 6-11 – first dose
0092A	Moderna Covid-19 vaccine administration – – children ages 6-11 – second dose
0093A	Moderna Covid-19 vaccine administration – – children ages 6-11 – third dose
91311	Moderna Covid-19 vaccine administration – children ages 6 months to 5 years
0111A	Moderna Covid-19 vaccine administration – children ages 6 months to 5 years – first dose

0112A	Moderna Covid-19 vaccine administration – – children ages 6 months to 5 years – second dose
0113A	Moderna Covid-19 vaccine administration – – children ages 6 months to 5 years – third dose
0083A	IMM ADMN SARSCOV2 3MCG/0.2ML TRIS-SUCROSE 3RD dose

15) Add the following CPT codes to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
    a. CPT 90611 Jynneos vaccine (Smallpox and monkeypox vaccine, attenuated vaccinia virus, live, non-replicating, preservative free, 0.5 mL dosage, suspension, for subcutaneous injection)
    b. CPT 90622 ACAM2000 vaccine (Vaccinia (smallpox) virus vaccine, live, lyophilized, 0.3 mL dosage, for percutaneous use)
16) Advise HSD to add CPT 87593 (Infectious agent detection by nucleic acid (DNA or RNA); orthopoxvirus (e.g., monkeypox virus, cowpox virus, vaccinia virus), amplified probe technique, each) to the DIAGNOSTIC PROCEDURES FILE
17) Modify GN106 as shown in appendix A
18) Move the S22.0[x][1-2] family and the S32.0[x][1-2] family (stable or unstable burst fractures of thoracic or lumbar spine) to line 150 CERVICAL VERTEBRAL DISLOCATIONS/FRACTURES, OPEN OR CLOSED; OTHER VERTEBRAL DISLOCATIONS/FRACTURES, OPEN OR UNSTABLE; SPINAL CORD INJURIES WITH OR WITHOUT EVIDENCE OF VERTEBRAL INJURY
19) Advise HSD to move the codes below to the Diagnostic Work Up File and remove from the Informational Diagnosis File

Z71.2	Person consulting for explanation of examination or test findings
Z72.51	High risk heterosexual behavior
Z72.52	High risk homosexual behavior
Z72.53	High risk bisexual behavior

20) Modify GN173 as shown in Appendix A

MOTION: To approve the recommendations stated in the consent agenda. CARRIES 6-0.

- **Topic: Tympanostomy guideline**

Discussion: Smits reviewed the summary document. There was minimal discussion. Dr. Peggy Kelley (OHSU) was present to answer questions.

Recommended Actions:
1) Add CPT 42830-42836 (Adenoidectomy primary or secondary) to line 389 ACUTE OTITIS MEDIA
2) Modify GN29 as shown in appendix A

MOTION: To recommend the code and guideline note changes as presented. CARRIES 6-0.

- **Topic: 2023 ICD-10-CM code review**

  Discussion: There was minimal discussion on this topic. The items discussed were:
  1) G90.A (Postural orthostatic tachycardia syndrome [POTS]) was placed on the dysfunction lines and line 535 HYPOTENSION
  2) The issue of possibly creating a new line for high risk for cancer was referred to the Genetics Advisory Panel.

  Recommended Actions:
  1) Place the 2023 ICD-10-CM codes to lines/lists as shown in Appendix B
  2) Add CPT 58520 (Hysterorrhaphy, repair of ruptured uterus (nonobstetrical)) to line 423 MENSTRUAL BLEEDING DISORDERS

  MOTION: To recommend the code and changes as modified. CARRIES 6-0.

- **Topic: 2024 Biennial Review: Temporomandibular Joint Syndrome prioritization**

  Discussion: There was minimal discussion on this topic.

  Recommended Actions:
  1) No changes to the current prioritization of temporomandibular joint syndrome.

- **Topic: Reproductive Health Equity Act 2022 report**

  Discussion: There was no discussion about this informational item.

- **Topic: Behavioral Health Advisory Panel Report straightforward items**

  Discussion: There was no discussion about these items.

  Recommended Actions:
  1) Remove the following HCPCS and CPT codes from all lines on the Prioritized List DIAGNOSTIC PROCEDURES FILE and advise HSD to add these codes to the DIAGNOSTIC PROCEDURES FILE

G0396	Alcohol and/or substance (other than tobacco) misuse structured assessment (e.g., audit, dast), and brief intervention 15 to 30 minutes
G0397	Alcohol and/or substance (other than tobacco) misuse structured assessment (e.g., audit, dast), and intervention, greater than 30 minutes
G2011	Alcohol and/or substance (other than tobacco) misuse structured assessment (e.g., audit, dast), and brief intervention, 5-14 minutes

  2) Remove HCPCS G0508 and G0509 (Telehealth consultation, critical care) from lines 203 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE, 438 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL

DISORDER, 450 REACTIVE ATTACHMENT DISORDER OF INFANCY OR EARLY CHILDHOOD, 471 ENCOPRESIS NOT DUE TO A PHYSIOLOGICAL CONDITION, and 523 SEXUAL DYSFUNCTION

3) Remove CPT 99225 and 99226 (Subsequent observation care, per day) from lines 192 AUTISM SPECTRUM DISORDERS, 252 PSYCHOLOGICAL FACTORS AGGRAVATING PHYSICAL CONDITION (E.G., ASTHMA, CHRONIC GI CONDITIONS, HYPERTENSION), and 575 PERSONALITY DISORDERS EXCLUDING BORDERLINE AND SCHIZOTYPAL
4) Add CPT 99225 to line 290 ACUTE STRESS DISORDER
5) Add CPT 90846 (Family psychotherapy (without the patient present), 50 minutes), 90847 (Family psychotherapy (conjoint psychotherapy) (with patient present), 50 minutes), 90849 (Multiple-family group psychotherapy), and 90853 (Group psychotherapy (other than of a multiple-family group)) to line 65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL
6) Add CPT 90785, 90832-90840 (Psychotherapy) to line 575 PERSONALITY DISORDERS EXCLUDING BORDERLINE AND SCHIZOTYPAL
7) Remove the following ICD-10-CM codes from line 606 DISORDERS OF SLEEP WITHOUT SLEEP APNEA and add to lines 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS and 377 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION

G25.70	Drug induced movement disorder, unspecified
G25.71	Drug induced akathisia
G25.79	Other drug induced movement disorders
G25.89	Other specified extrapyramidal and movement disorders
G26	Extrapyramidal and movement disorders in diseases classified elsewhere

8) Add ICD-10-CM G25.9 (Extrapyramidal and movement disorder, unspecified) to lines 292 and 377 and remove from lines 362 DYSTONIA (UNCONTROLLABLE); LARYNGEAL SPASM and line 71 and 345 (dysfunction lines)

MOTION: To recommend the code changes as presented. CARRIES 6-0.

- **Topic: Behavioral Health Advisory Panel Report: Conduct disorder**

Discussion: There was minimal discussion on this topic.

Recommended Actions:

1) Add ICD-10-CM F91.0-F91.2, and F91.8 (Conduct disorder) to line 420 OPPOSITIONAL DEFIANT DISORDER
2) Add ICD-10-CM F63.81 (Intermittent explosive disorder) to line 420 and remove from line 547 IMPULSE DISORDERS
3) Change the name of line 420 to OPPOSITIONAL DEFIANT DISORDER; CONDUCT DISORDER AGE 18 OR UNDER
4) Strike through line 479
5) Modify guideline note 54 as shown in appendix A
6) Delete guideline note 152
7) Effective 1/1/24

i. Delete line 479 CONDUCT DISORDER, AGE 18 OR UNDER

MOTION: To recommend the code and guideline note changes as presented. CARRIES 6-0.

- **Topic: Behavioral Health Advisory Panel Report: Insomnia**

Discussion: Smits reviewed the summary document. There was general concern about long-term use of sedative-hypnotic medications for any condition. The exclusion for patients with other psychiatric illness or on continuous positive airway pressure (CPAP) was removed from the proposed guideline. There was also concern about defining long term use as greater than 3 months. This was felt to be too long, and put patients at high risk of becoming dependent on these medications. The decision was to modify the proposed guideline to define long term as great than 1 month per year.

Recommended Actions:

1) Effective January 1, 2024:
    a. Add the following ICD-10-CM codes to Line 202 SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER and delete from Line 606 DISORDERS OF SLEEP WITHOUT SLEEP APNEA
        i. F51.01 Primary insomnia
        ii. F51.02 Adjustment insomnia
        iii. F51.03 Paradoxical insomnia
        iv. F51.04 Psychophysiologic insomnia
        v. F51.05 Insomnia due to other mental disorder
        vi. F51.09 Other insomnia not due to a substance or known physiological condition
        vii. G47.00 Insomnia, unspecified
        viii. G47.01 Insomnia due to medical condition
        ix. G47.09 Other insomnia
    b. Rename line 202 SLEEP APNEA, NARCOLEPSY, INSOMNIA AND REM BEHAVIORAL DISORDER for the January 1, 2024, Prioritized List
    c. Add the CPT codes for cognitive behavioral therapy to line 202
        i. 90785 Interactive complexity
        ii. 90832-90838 Psychotherapy
        iii. 90853 Group psychotherapy (other than of a multiple-family group)
    d. Adopt a new guideline for line 202 as shown in appendix A

MOTION: To recommend the code and guideline note changes as modified. CARRIES 6-0.

- **Topic: Autoimmune encephalitis**

Discussion: There was minimal discussion about this item.

Recommended Actions:

1) Add ICD-10-CM G04.81 (Other encephalitis and encephalomyelitis) to line 313 DISORDERS INVOLVING THE IMMUNE SYSTEM
    a. Remove G04.81 from line 536 VIRAL, SELF-LIMITING ENCEPHALITIS, MYELITIS AND ENCEPHALOMYELITIS.

2) Modify the new guideline regarding PANDAS and PANS as shown in appendix C

MOTION: To recommend the code and guideline note changes as presented. CARRIES 6-0.

- **Topic: Inflammatory skin disease guideline**

Discussion: Smits reviewed the summary document and staff recommendation. There was concern among subcommittee members that removing the medications from the guideline would result in coordinated care organizations (CCOs) having different coverage criteria, which would create inconsistent coverage across the state. Additionally, Hodges noted that CCO pharmacy and therapeutic (P&T) groups could not review this drug class any more rapidly that the HERC could make guideline note changes. Gingerich noted that HERC cannot, by statute, conduct a drug class review; however, the subcommittee felt that P&T could conduct the drug class review and HERC staff could use that to inform the guideline.

HERC staff was directed to work with OHA P&T staff on this guideline and bring back to a future meeting.

- **Topic: Microsatellite instability testing**

Discussion: Smits reviewed the summary document, with a friendly staff amendment that corrected the CPT under consideration to 81301 (meeting materials contained CPT 81302). It was noted that this is a test on cancer tissue, and the CPT code should be placed on the colon cancer line rather than the diagnostic procedures file. The guideline note was also modified to reflect that this code is on the colon cancer line.

The discussion then turned to whether the 2015 coverage guidance on biomarker tests of cancer tissue should be retired or updated. The group strongly felt that this coverage guidance was useful and should be updated. There was some discussion of using NCCN guidelines instead, but there was concern that some NCCN guideline recommendations are not strong and may not be evidence based. There was a perceived need for coverage uniformity across CCOs, which would be best accomplished through a coverage guidance.

King from the CEBP asked which particular tests or conditions were of interest to HERC and what outcomes were critical to decision making. It was felt that the outcome of most interest would be predictive outcomes (whether a test would change treatment decision). King asked about mortality as an outcome; the group felt that would be appropriate only as a result of a changed treatment choice. There was discussion about which guidelines the CEBP should consider. NCCN, ASCO and CAP (College of American Pathologists) guidelines were suggested. There was also discussion about what level of NCCN recommendation should be considered, and Olson felt that it should be IIA and above. Olson recommended that CEBP use the scope statement from the 2015 coverage review as it is likely what is of current interest.

Public testimony
Denis McCarthy, pathologist in Springfield, Oregon: Dr. McCarthy declared he had no financial relationship with any vendors or pharmaceuticals. He has expertise with screening for Lynch

syndrome and testing has evolved over the past few years, such as determining eligibility for immune checkpoint inhibitors. His recommendation was to perform a combination of MSI testing and pathologic tissue testing. MSI testing uses much less tissue to get a result than alternative molecular tests. MSI is a tool to minimize use of precious tissue and to avoid additional diagnostic procedures, which are both expensive and have risks to the patient.

Recommended Actions:

1) Remove CPT 81301 (Microsatellite instability analysis (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) of markers for mismatch repair deficiency (e.g., BAT25, BAT26), includes comparison of neoplastic and normal tissue, if performed) from line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
    a. Add 81301 to line 157 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS
2) Modify GN 148 as shown in Appendix A
3) Modify GN 173 as shown in Appendix A
4) Recommend to HERC to take up a revision of the coverage guidance on biomarkers test of cancer tissue

MOTION: To recommend the code and guideline note changes as modified. CARRIES 6-0.

- **Topic: Scoliosis guideline**

Discussion: Smits reviewed the summary document.

Public testimony

Josiah Orina, OHSU neurosurgeon specializing in spine surgery: Dr. Orina testified that adolescent idiopathic scoliosis can be diagnosed in adulthood, when it is called adult idiopathic scoliosis. He has patients who are older than age 20 with adolescent idiopathic scoliosis and meet criteria for surgery. Scoliosis guidelines recommend surgery for patients with a curve of 45 degrees or greater who are skeletally immature. Surgery could also be performed on adults who are skeletally mature with a curve of greater than 50 degrees or have progression over time.

The subcommittee requested that the guideline should be amended further to include adult idiopathic scoliosis (ICD-10-CM M41.2 family).

Recommended Actions:

1) Modify GN 41 as shown in Appendix A

MOTION: To recommend the guideline note changes as modified. CARRIES 6-0.

- **Topic: Canaloplasty for glaucoma**

Discussion: There was no discussion about this item.

Recommended Actions:

1) Add CPT 66174 Transluminal dilation of aqueous outflow canal; without retention of device or stent and CPT 66175 Transluminal dilation of aqueous outflow canal; with retention of device or stent to line 139 GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE
    a. Remove CPT 66174 and 66175 from line 662
2) Modify GN173 as shown in appendix A

MOTION: To recommend the code and guideline note changes as modified. CARRIES 6-0.

- **Topic: Coverage Guidance—High-frequency Chest Wall Oscillation Devices**

Discussion: Val King from CEBP presented the evidence summary and Smits reviewed the values and preferences as well as staff recommendations.

Public testimony

Gary Hansen, Director of Scientific Affairs for Respirtech (manufacturer): Mr. Hansen noted that the staff recommendation did not include Line 58 BRONCHIECTASIS. Staff acknowledged this mistake and recommended modifying staff recommendations to include adding the required CPT and HCPCS codes to Line 58.

Hodges noted that these devices are expensive and that many of the requests she receives for these devices are for adolescents who are not willing to participate in any treatment. Olson noted that there is low evidence but vulnerable populations.

Recommended Actions:

1) Delete CPT 94669 (Mechanical chest wall oscillation to facilitate lung function, per session) from line 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS
2) Modify GN172 as shown in Appendix A
3) Add CPT 94669 to lines 20 CYSTIC FIBROSIS, 58 BRONCHIECTASIS, 71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES, and 197 CONGENITAL LUNG ANOMALIES
4) Add HCPCS A7025 (High frequency chest wall oscillation system vest, replacement for use with patient owned equipment, each), A7026 (High frequency chest wall oscillation system hose, replacement for use with patient owned equipment, each), and E0483 (High frequency chest wall oscillation system, includes all accessories and supplies, each) to lines 20 CYSTIC FIBROSIS, 58 BRONCHIECTASIS, 71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES and 197 CONGENITAL LUNG ANOMALIES
5) Add a new guideline to lines 20, 58, 71, and 197 as shown in Appendix A

MOTION: To approve the amended changes to the Prioritized List based on the draft High Frequency Chest Wall Oscillation coverage guidance scheduled for review by HERC at their 8/11/2022 meeting. CARRIES 6-0.

- **Public Comment:**

  Devin Fakner, Business Development Manager of Biotech Healthcare (manufacturer of pneumatic compression devices): Mr. Fakner disclosed he works for a company that makes pneumatic compression devices for lymphedema and chronic venous insufficiency. He stated this is a medical necessary adjunct treatment for patients with lymphedema, who are high-cost patients with limited treatment options. He described a study that showed patients receiving a combination of lymphedema therapy and at-home pneumatic compression devices had decreased symptoms, risk of infection, and rate of hospitalization compared to lymphedema therapy alone. Fakner said these devices improve quality of life and reducing secondary complications. The use and demand of these devices has increased rapidly over the past 30 years.

- **Issues for next meeting:**
  -Inflammatory skin disease guideline update

- **Next meeting:**

  October 6, 2022, virtual meeting

- **Adjournment:**

  The meeting adjourned at 12:45 PM.

Appendix A

Revised Guideline Notes

GUIDELINE NOTE 3, PROPHYLACTIC TREATMENT FOR PREVENTION OF BREAST CANCER IN HIGH-RISK WOMEN

Line 191

Bilateral prophylactic breast removal and/or salpingo-oophorectomy are included on Line 191 for women without a personal history of invasive breast cancer who meet the criteria in the NCCN Clinical Practice Guidelines in Oncology (Genetic/Familial High-Risk Assessment: Breast, Ovarian and Pancreatic V1.2022 (8/11/21) www.nccn.org). Prior to surgery, women without a personal history of breast cancer must have a genetics consultation as defined in section ~~A2~~ B of the DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE.

Contralateral prophylactic mastectomy is included on Line 191 for women with a personal history of breast cancer.

Hysterectomy is only included on Line 191 for women with a BRCA1 pathogenic/likely pathogenic variant who undergo the procedure at the time of risk reducing salpingo-oophrectomy

~~GUIDELINE NOTE 9~~ DIAGNOSTIC GUIDELINE DX, WIRELESS CAPSULE ENDOSCOPY

~~Lines 29,56~~

A) Wireless capsule endoscopy is included on these lines for diagnosis of:
   1) Obscure GI bleeding suspected to be of small bowel origin with iron deficiency anemia or documented GI blood loss
   2) Suspected Crohn's disease with prior negative work up

B) Wireless capsule endoscopy is not included on these lines for:
   1) Colorectal cancer screening
   2) Confirmation of lesions of pathology normally within the reach of upper or lower endoscopes (lesions proximal to the ligament of Treitz or distal to the ileum)

C) Wireless capsule endoscopy is only included on these lines when the following conditions have been met:
   1) Prior studies must have been performed and been non-diagnostic
      a) GI bleeding: upper and lower endoscopy
      b) Suspected Crohn's disease: upper and lower endoscopy, small bowel follow through
   2) Radiological evidence of lack of stricture
   3) Only covered once during any episode of illness
   4) FDA approved devices must be used
   5) Patency capsule should not be used prior to procedure

GUIDELINE NOTE 29, TYMPANOSTOMY TUBES IN ACUTE OTITIS MEDIA

Line 389

Tympanostomy tubes (CPT 69433, 69436) are only included on this line as treatment for:

A) recurrent acute otitis media (three or more well-documented and separate episodes in six months or four or more well-documented and separate episodes in the past 12 months with at least one episode in the past six months) in patients who have unilateral or bilateral middle ear effusion at the time of assessment for tube candidacy, or

B) patients with complicating conditions (atelectasis [collapsed eardrum], immunocompromised host, meningitis by lumbar puncture, acute mastoiditis, sigmoid sinus/jugular vein thrombosis by CT/MRI/MRA, cranial nerve paralysis, sudden onset dizziness/vertigo, need for middle ear culture, labyrinthitis, or brain abscess).

Patients with craniofacial anomalies; syndromes~~,~~ ~~Down's syndrome~~ that include cognitive, speech, or language delays; cleft palate~~,~~; permanent hearing loss of 25dB or greater independent of otitis media with effusion~~,~~; developmental delay; intellectual disability~~,~~; learning disorder~~,~~; attention-deficit/hyperactivity disorder~~,~~; blindness or uncorrectable visual impairment~~,~~; and patients with speech and language delay may be considered for tympanostomy if unresponsive to appropriate medical treatment or having recurring infections (without needing to meet the strict "recurrent" definition above).

Adenoidectomy is included on these lines at the time of tympanostomy tube insertion for children under age 4 with symptoms directly related to the adenoids (for example, ear infection associated with rhinorrhea and/or upper respiratory infection) OR in children aged 4 years or older.

Removal of retained tympanostomy tubes requiring anesthesia (CPT code 69424) or as an office visit, is included on Line 424 as a complication, pairing with ICD-10-CM H74.8.

The development of this guideline note was informed by a HERC coverage guidance. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx

GUIDELINE NOTE 41, SCOLIOSIS

Line 361

Non-surgical treatments of scoliosis (ICD-10-CM M41) are included on Line 361 when

1) the scoliosis is considered clinically significant, defined as curvature greater than or equal to 25 degrees, or
2) there is curvature with a documented rapid progression.

Surgical treatments of adolescent and adult idiopathic scoliosis (ICD-10-CM M41.1 and M41.2 families) are included on Line 361 only for

~~1) only for children and adolescents (age 20 and younger) with~~

2) patients with documented failure of non-operative management; AND
3) a spinal curvature of greater than 45 degrees

GUIDELINE NOTE 54, CONDUCT DISORDER

Line 420~~, 479~~

Conduct disorder rarely occurs in isolation from other psychiatric diagnosis, the patient should have documented screening (or documented refusal to be screened) for attention deficit/hyperactivity disorder (ADHD); chemical dependency (CD); mood disorders such as anxiety and/or depression; and physical, sexual, and family abuse or other trauma (PTSD).

ICD-10-CM F91.9 (Conduct disorder, unspecified) is included on Line 420 only for children ages 5 and younger who cannot be diagnosed with a more specific mental health diagnosis.

Appendix A

GUIDELINE NOTE 106, PREVENTIVE SERVICES

Lines 3,622

Included on Line 3 are the following preventive services:

A) US Preventive Services Task Force (USPSTF) "A" and "B" Recommendations in effect and issued prior to January 1, ~~2021~~ 2022.
   1) ~~http://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/~~ https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendation
      a) Treatment of falls prevention with exercise interventions is included on Line 292.
   2) USPSTF "D" recommendations are not included on this line or any other line of the Prioritized List.

B) American Academy of Pediatrics (AAP) Bright Futures Guidelines:
   1) http://brightfutures.aap.org. Periodicity schedule available at ~~http://www.aap.org/en-us/professional-resources/practice-support/Periodicity/Periodicity Schedule_FINAL.pdf.~~ https://downloads.aap.org/AAP/PDF/periodicity_schedule.pdf
      a) Bright Futures is the periodicity schedule for screening for EPSDT for the Oregon Health Plan.
   2) Screening for lead levels is defined as blood lead level testing and is indicated for Medicaid populations at 12 and 24 months. In addition, blood lead level screening of any child between ages 24 and 72 months with no record of a previous blood lead screening test is indicated.

C) Health Resources **and Services Administration (HRSA) Women's Preventive Services-Required Health Plan Coverage Guidelines (revised January, 2022)** ~~as updated by HRSA in December 2019~~. Available at https://www.hrsa.gov/womens-guidelines ~~2019~~ retrieved on July 28, 2022 ~~of September 4, 2020~~.

D) Immunizations as recommended by the Advisory Committee on Immunization Practices (ACIP): http://www.cdc.gov/vaccines/schedules/hcp/index.html or approved for the Oregon Immunization Program: https://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/Documents/DMAPvactable.pdf
   1) COVID-19 vaccines are intended to be included on this line even if the specific administration code(s) do not yet appear on the line when the vaccine has both 1) FDA approval or FDA emergency use authorization (EUA) and 2) ACIP recommendation.

Colorectal cancer screening is included on Line 3 for average-risk adults aged 45 to 75, using one of the following screening programs:

A) Colonoscopy every 10 years
B) Flexible sigmoidoscopy every 5 years
C) Fecal immunochemical test (FIT) every year
D) Guaiac-based fecal occult blood test (gFOBT) every year

CT colonography (CPT 74263), FIT-DNA (CPT 81528) and mSEPT9 (HCPCS G0327) are included on Line 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS.

Appendix A

Colorectal cancer screening for average-risk adults aged 76 to 85 is covered after informed decision making between patients and clinicians which includes consideration of the patient's overall health, prior screening history, and preferences.

Supervised evidence-based exercise programs for fall prevention for persons aged 65 or older OR younger patients who are at increased risk of falls are included on Line 3 using CPT 98961 or 98962 or HCPCS S9451. HCPCS S9451 is only included on Line 3 for the provision of supervised exercise therapy for fall prevention. Programs should be culturally tailored/culturally appropriate when feasible.

Note: CPT 96110 (Developmental screening (e.g., developmental milestone survey, speech and language delay screen), with scoring and documentation, per standardized instrument) can be billed in addition to other CPT codes, such as evaluation and management (E&M) codes or preventive visit codes.

The development of this guideline note was informed by a HERC coverage guidance. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx

GUIDELINE NOTE 148, BIOMARKER TESTS OF CANCER TISSUE

Lines 157,184,191,229,262,271,329

The use of tissue of origin testing (e.g. CPT 81504) is included on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.

For early stage breast cancer, the following breast cancer genome profile tests are included on Line 191 when the listed criteria are met. One test per primary breast cancer is covered when the patient is willing to use the test results in a shared decision-making process regarding adjuvant chemotherapy. Lymph nodes with micrometastases less than 2 mm in size are considered node negative.

- Oncotype DX Breast Recurrence Score (CPT 81519) for breast tumors that are estrogen receptor positive, HER2 negative, and either lymph node negative, or lymph node positive with 1-3 involved nodes.
- EndoPredict (CPT 81522) and Prosigna (CPT 81520 or PLA 0008M) for breast tumors that are estrogen receptor positive, HER2 negative, and lymph node negative.
- MammaPrint (using CPT 81521, 81523 or HCPCS S3854) for breast tumors that are estrogen receptor or progesterone receptor positive, HER2 negative, lymph node negative, and only in those cases categorized as high clinical risk.

For early stage breast cancer that is estrogen receptor positive, HER2 negative, and either lymph node negative or lymph node positive with 1-3 involved nodes, Breast Cancer Index (CPT 81518) is included on Line 191 when the patient is willing to use the test results in a shared decision-making process regarding prolonged adjuvant endocrine therapy.

EndoPredict, Prosigna, and MammaPrint are not included on Line 191 for early-stage breast cancer with involved axillary lymph nodes. Oncotype DX Breast Recurrence Score is not included on Line 191 for breast cancer involving four or more axillary lymph nodes or more extensive metastatic disease.

Appendix A

Oncotype DX Breast DCIS Score (CPT 81479) is included on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.

For melanoma, BRAF gene mutation testing (CPT 81210) is included on Line 229. DecisionDx-Melanoma (CPT 81529) is included on Line 662.

For lung cancer, epidermal growth factor receptor (EGFR) gene mutation testing (CPT 81235) is included on Line 262 only for non-small cell lung cancer. KRAS gene mutation testing (CPT 81275) is not included on this line.

For colorectal cancer, KRAS gene mutation testing (CPT 81275) is included on Line 157. BRAF (CPT 81210) and Oncotype DX are not included on this line. Microsatellite instability (MSI) is included on ~~Line 662.~~ line 157.

For bladder cancer, Urovysion testing is included on Line 662.

For prostate cancer, Oncotype DX Genomic Prostate Score, Prolaris Score Assay (CPT 81541), and Decipher Prostate RP (CPT 81542) are included on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.

For thyroid cancer, Afirma gene expression classifier (CPT 81546) is included on Line 662.

The development of this guideline note was informed by a HERC coverage guidance on Biomarkers Tests of Cancer Tissue for Prognosis and Potential Response to Treatment; the prostate-related portion of that coverage guidance was superseded by a Coverage Guidance on Gene Expression Profiling for Prostate Cancer. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx

~~**GUIDELINE NOTE 152, UNSPECIFIED CONDUCT DISORDER**~~

~~*Lines 420,479*~~

~~ICD-10-CM F91.9 (Conduct disorder, unspecified) is included on Line 420 only for children ages 5 and younger who cannot be diagnosed with a more specific mental health diagnosis. This diagnosis is included on Line 479 for older children and adolescents~~.

GUIDELINE NOTE 172, INTERVENTIONS WITH MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS FOR CERTAIN CONDITIONS

Line 502

The following interventions are prioritized on Line 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS:

Procedure Code	Intervention Description	Rationale	Last Review
~~94669~~	~~Mechanical chest wall oscillation~~	~~More costly than equally effective therapies~~	~~October, 2016~~

Appendix A

GUIDELINE NOTE 173, INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS

Line 662

The following Interventions are prioritized on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
31660-31661	Bronchial thermoplasty	Insufficient evidence of effectiveness	~~January, 2014~~ August 2022
~~66174 66175~~	~~Transluminal dilation of aqueous outflow canal~~	~~Insufficient evidence of effectiveness~~	~~December, 2010~~
~~81301~~	~~Microsatellite instability (MSI) for colorectal cancer~~	~~Unproven intervention~~	~~August, 2015~~

Appendix B
New Codes

ICD10 Code	Code Description	Recommended Placement
B37.31	Acute candidiasis of vulva and vagina	428 VAGINITIS AND CERVICITIS
B37.32	Chronic candidiasis of vulva and vagina	428 VAGINITIS AND CERVICITIS
D59.30	Hemolytic-uremic syndrome, unspecified	99 END STAGE RENAL DISEASE 148 ACQUIRED HEMOLYTIC ANEMIAS
D59.31	Infection-associated hemolytic-uremic syndrome	99 END STAGE RENAL DISEASE 148 ACQUIRED HEMOLYTIC ANEMIAS
D59.32	Hereditary hemolytic-uremic syndrome	99 END STAGE RENAL DISEASE 148 ACQUIRED HEMOLYTIC ANEMIAS
D59.39	Other hemolytic-uremic syndrome	99 END STAGE RENAL DISEASE 148 ACQUIRED HEMOLYTIC ANEMIAS
D68.00	Von Willebrand disease, unspecified	109 COAGULATION DEFECTS
D68.01	Von Willebrand disease, type 1	109 COAGULATION DEFECTS
D68.020	Von Willebrand disease, type 2A	109 COAGULATION DEFECTS
D68.021	Von Willebrand disease, type 2B	109 COAGULATION DEFECTS
D68.022	Von Willebrand disease, type 2M	109 COAGULATION DEFECTS
D68.023	Von Willebrand disease, type 2N	109 COAGULATION DEFECTS
D68.029	Von Willebrand disease, type 2, unspecified	109 COAGULATION DEFECTS
D68.03	Von Willebrand disease, type 3	109 COAGULATION DEFECTS
D68.04	Acquired von Willebrand disease	109 COAGULATION DEFECTS
D68.09	Other von Willebrand disease	109 COAGULATION DEFECTS
D75.821	Non-immune heparin-induced thrombocytopenia	303 THROMBOCYTOPENIA
D75.822	Immune-mediated heparin-induced thrombocytopenia	303 THROMBOCYTOPENIA
D75.828	Other heparin-induced thrombocytopenia syndrome	303 THROMBOCYTOPENIA
D75.829	Heparin-induced thrombocytopenia, unspecified	303 THROMBOCYTOPENIA
D75.84	Other platelet-activating anti-PF4 disorders	303 THROMBOCYTOPENIA
D81.82	Activated Phosphoinositide 3-kinase Delta Syndrome [APDS]	313 DISORDERS INVOLVING THE IMMUNE SYSTEM
E34.30	Short stature due to endocrine disorder, unspecified	652 ENDOCRINE AND METABOLIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
E34.31	Constitutional short stature	652 ENDOCRINE AND METABOLIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
E34.321	Primary insulin-like growth factor-1 (IGF-1) deficiency	652 ENDOCRINE AND METABOLIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

Appendix B
New Codes

ICD10 Code	Code Description	Recommended Placement
E34.322	Insulin-like growth factor-1 (IGF-1) resistance	652 ENDOCRINE AND METABOLIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
E34.328	Other genetic causes of short stature	652 ENDOCRINE AND METABOLIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
E34.329	Unspecified genetic causes of short stature	652 ENDOCRINE AND METABOLIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
E34.39	Other short stature due to endocrine disorder	652 ENDOCRINE AND METABOLIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
E87.20	Acidosis, unspecified	221 DISORDERS OF FLUID, ELECTROLYTE, AND ACID-BASE BALANCE
E87.21	Acute metabolic acidosis	221 DISORDERS OF FLUID, ELECTROLYTE, AND ACID-BASE BALANCE
E87.22	Chronic metabolic acidosis	221 DISORDERS OF FLUID, ELECTROLYTE, AND ACID-BASE BALANCE
E87.29	Other acidosis	221 DISORDERS OF FLUID, ELECTROLYTE, AND ACID-BASE BALANCE

Appendix B
New Codes

ICD10 Code	Code Description	Recommended Placement
F01.511	Vascular dementia, unspecified severity, with agitation	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 201 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS 377 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
F01.518	Vascular dementia, unspecified severity, with other behavioral disturbance	71,201,292,345,377
F01.52	Vascular dementia, unspecified severity, with psychotic disturbance	71,201,292,345,377
F01.53	Vascular dementia, unspecified severity, with mood disturbance	71,201,292,345,377
F01.54	Vascular dementia, unspecified severity, with anxiety	71,201,292,345,377
F01.A0	Vascular dementia, mild, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety	71,201,292,345,377
F01.A11	Vascular dementia, mild, with agitation	71,201,292,345,377
F01.A18	Vascular dementia, mild, with other behavioral disturbance	71,201,292,345,377
F01.A2	Vascular dementia, mild, with psychotic disturbance	71,201,292,345,377
F01.A3	Vascular dementia, mild, with mood disturbance	71,201,292,345,377
F01.A4	Vascular dementia, mild, with anxiety	71,201,292,345,377
F01.B0	Vascular dementia, moderate, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety	71,201,292,345,377
F01.B11	Vascular dementia, moderate, with agitation	71,201,292,345,377

Appendix B
New Codes

ICD10 Code	Code Description	Recommended Placement
F01.B18	Vascular dementia, moderate, with other behavioral disturbance	71,201,292,345,377
F01.B2	Vascular dementia, moderate, with psychotic disturbance	71,201,292,345,377
F01.B3	Vascular dementia, moderate, with mood disturbance	71,201,292,345,377
F01.B4	Vascular dementia, moderate, with anxiety	71,201,292,345,377
F01.C0	Vascular dementia, severe, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety	71,201,292,345,377
F01.C11	Vascular dementia, severe, with agitation	71,201,292,345,377
F01.C18	Vascular dementia, severe, with other behavioral disturbance	71,201,292,345,377
F01.C2	Vascular dementia, severe, with psychotic disturbance	71,201,292,345,377
F01.C3	Vascular dementia, severe, with mood disturbance	71,201,292,345,377
F01.C4	Vascular dementia, severe, with anxiety	71,201,292,345,377
F02.811	Dementia in other diseases classified elsewhere, unspecified severity, with agitation	71,201,292,345,377
F02.818	Dementia in other diseases classified elsewhere, unspecified severity, with other behavioral disturbance	71,201,292,345,377
F02.82	Dementia in other diseases classified elsewhere, unspecified severity, with psychotic disturbance	71,201,292,345,377
F02.83	Dementia in other diseases classified elsewhere, unspecified severity, with mood disturbance	71,201,292,345,377
F02.84	Dementia in other diseases classified elsewhere, unspecified severity, with anxiety	71,201,292,345,377
F02.A0	Dementia in other diseases classified elsewhere, mild, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety	71,201,292,345,377
F02.A11	Dementia in other diseases classified elsewhere, mild, with agitation	71,201,292,345,377
F02.A18	Dementia in other diseases classified elsewhere, mild, with other behavioral disturbance	71,201,292,345,377

Appendix B
New Codes

ICD10 Code	Code Description	Recommended Placement
F02.A2	Dementia in other diseases classified elsewhere, mild, with psychotic disturbance	71,201,292,345,377
F02.A3	Dementia in other diseases classified elsewhere, mild, with mood disturbance	71,201,292,345,377
F02.A4	Dementia in other diseases classified elsewhere, mild, with anxiety	71,201,292,345,377
F02.B0	Dementia in other diseases classified elsewhere, moderate, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety	71,201,292,345,377
F02.B11	Dementia in other diseases classified elsewhere, moderate, with agitation	71,201,292,345,377
F02.B18	Dementia in other diseases classified elsewhere, moderate, with other behavioral disturbance	71,201,292,345,377
F02.B2	Dementia in other diseases classified elsewhere, moderate, with psychotic disturbance	71,201,292,345,377
F02.B3	Dementia in other diseases classified elsewhere, moderate, with mood disturbance	71,201,292,345,377
F02.B4	Dementia in other diseases classified elsewhere, moderate, with anxiety	71,201,292,345,377
F02.C0	Dementia in other diseases classified elsewhere, severe, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety	71,201,292,345,377
F02.C11	Dementia in other diseases classified elsewhere, severe, with agitation	71,201,292,345,377
F02.C18	Dementia in other diseases classified elsewhere, severe, with other behavioral disturbance	71,201,292,345,377
F02.C2	Dementia in other diseases classified elsewhere, severe, with psychotic disturbance	71,201,292,345,377
F02.C3	Dementia in other diseases classified elsewhere, severe, with mood disturbance	71,201,292,345,377
F02.C4	Dementia in other diseases classified elsewhere, severe, with anxiety	71,201,292,345,377
F03.911	Unspecified dementia, unspecified severity, with agitation	71,201,292,345,377
F03.918	Unspecified dementia, unspecified severity, with other behavioral disturbance	71,201,292,345,377

Appendix B
New Codes

ICD10 Code	Code Description	Recommended Placement
F03.92	Unspecified dementia, unspecified severity, with psychotic disturbance	71,201,292,345,377
F03.93	Unspecified dementia, unspecified severity, with mood disturbance	71,201,292,345,377
F03.94	Unspecified dementia, unspecified severity, with anxiety	71,201,292,345,377
F03.A0	Unspecified dementia, mild, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety	71,201,292,345,377
F03.A11	Unspecified dementia, mild, with agitation	71,201,292,345,377
F03.A18	Unspecified dementia, mild, with other behavioral disturbance	71,201,292,345,377
F03.A2	Unspecified dementia, mild, with psychotic disturbance	71,201,292,345,377
F03.A3	Unspecified dementia, mild, with mood disturbance	71,201,292,345,377
F03.A4	Unspecified dementia, mild, with anxiety	71,201,292,345,377
F03.B0	Unspecified dementia, moderate, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety	71,201,292,345,377
F03.B11	Unspecified dementia, moderate, with agitation	71,201,292,345,377
F03.B18	Unspecified dementia, moderate, with other behavioral disturbance	71,201,292,345,377
F03.B2	Unspecified dementia, moderate, with psychotic disturbance	71,201,292,345,377
F03.B3	Unspecified dementia, moderate, with mood disturbance	71,201,292,345,377
F03.B4	Unspecified dementia, moderate, with anxiety	71,201,292,345,377
F03.C0	Unspecified dementia, severe, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety	71,201,292,345,377
F03.C11	Unspecified dementia, severe, with agitation	71,201,292,345,377
F03.C18	Unspecified dementia, severe, with other behavioral disturbance	71,201,292,345,377
F03.C2	Unspecified dementia, severe, with psychotic disturbance	71,201,292,345,377
F03.C3	Unspecified dementia, severe, with mood disturbance	71,201,292,345,377

Appendix B
New Codes

ICD10 Code	Code Description	Recommended Placement
F03.C4	Unspecified dementia, severe, with anxiety	71,201,292,345,377
F06.70	Mild neurocognitive disorder due to known physiological condition without behavioral disturbance	71,201,292,345,377
F06.71	Mild neurocognitive disorder due to known physiological condition with behavioral disturbance	71,201,292,345,377
F10.90	Alcohol use, unspecified, uncomplicated	649 MENTAL DISORDERS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
F10.91	Alcohol use, unspecified, in remission	4 SUBSTANCE USE DISORDER
F11.91	Opioid use, unspecified, in remission	4 SUBSTANCE USE DISORDER
F12.91	Cannabis use, unspecified, in remission	4 SUBSTANCE USE DISORDER
F13.91	Sedative, hypnotic or anxiolytic use, unspecified, in remission	4 SUBSTANCE USE DISORDER
F14.91	Cocaine use, unspecified, in remission	4 SUBSTANCE USE DISORDER
F15.91	Other stimulant use, unspecified, in remission	4 SUBSTANCE USE DISORDER
F16.91	Hallucinogen use, unspecified, in remission	4 SUBSTANCE USE DISORDER
F18.91	Inhalant use, unspecified, in remission	4 SUBSTANCE USE DISORDER
F19.91	Other psychoactive substance use, unspecified, in remission	4 SUBSTANCE USE DISORDER
F43.81	Prolonged grief disorder	445 ADJUSTMENT DISORDERS
F43.89	Other reactions to severe stress	445 ADJUSTMENT DISORDERS
G71.031	Autosomal dominant limb girdle muscular dystrophy	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS 377 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
G71.032	Autosomal recessive limb girdle muscular dystrophy due to calpain-3 dysfunction	71,292,345,377

Appendix B
New Codes

ICD10 Code	Code Description	Recommended Placement
G71.033	Limb girdle muscular dystrophy due to dysferlin dysfunction	71,292,345,377
G71.0340	Limb girdle muscular dystrophy due to sarcoglycan dysfunction, unspecified	71,292,345,377
G71.0341	Limb girdle muscular dystrophy due to alpha sarcoglycan dysfunction	71,292,345,377
G71.0342	Limb girdle muscular dystrophy due to beta sarcoglycan dysfunction	71,292,345,377
G71.0349	Limb girdle muscular dystrophy due to other sarcoglycan dysfunction	71,292,345,377
G71.035	Limb girdle muscular dystrophy due to anoctamin-5 dysfunction	71,292,345,377
G71.038	Other limb girdle muscular dystrophy	71,292,345,377
G71.039	Limb girdle muscular dystrophy, unspecified	71,292,345,377
G90.A	Postural orthostatic tachycardia syndrome [POTS]	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS 377 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION 535 HYPOTENSION
G93.31	Postviral fatigue syndrome	531 FIBROMYALGIA, CHRONIC FATIGUE SYNDROME, AND RELATED DISORDERS
G93.32	Myalgic encephalomyelitis/chronic fatigue syndrome	531 FIBROMYALGIA, CHRONIC FATIGUE SYNDROME, AND RELATED DISORDERS
G93.39	Other post infection and related fatigue syndromes	531 FIBROMYALGIA, CHRONIC FATIGUE SYNDROME, AND RELATED DISORDERS
I20.2	Refractory angina pectoris	189 CHRONIC ISCHEMIC HEART DISEASE

Appendix B
New Codes

ICD10 Code	Code Description	Recommended Placement
I25.112	Atherosclerosic heart disease of native coronary artery with refractory angina pectoris	189 CHRONIC ISCHEMIC HEART DISEASE
I25.702	Atherosclerosis of coronary artery bypass graft(s), unspecified, with refractory angina pectoris	189 CHRONIC ISCHEMIC HEART DISEASE
I25.712	Atherosclerosis of autologous vein coronary artery bypass graft(s) with refractory angina pectoris	189 CHRONIC ISCHEMIC HEART DISEASE
I25.722	Atherosclerosis of autologous artery coronary artery bypass graft(s) with refractory angina pectoris	189 CHRONIC ISCHEMIC HEART DISEASE
I25.732	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with refractory angina pectoris	189 CHRONIC ISCHEMIC HEART DISEASE
I25.752	Atherosclerosis of native coronary artery of transplanted heart with refractory angina pectoris	189 CHRONIC ISCHEMIC HEART DISEASE
I25.762	Atherosclerosis of bypass graft of coronary artery of transplanted heart with refractory angina pectoris	189 CHRONIC ISCHEMIC HEART DISEASE
I25.792	Atherosclerosis of other coronary artery bypass graft(s) with refractory angina pectoris	189 CHRONIC ISCHEMIC HEART DISEASE
I31.31	Malignant pericardial effusion in diseases classified elsewhere	81 MYOCARDITIS, PERICARDITIS, AND ENDOCARDITIS
I31.39	Other pericardial effusion (noninflammatory)	81 MYOCARDITIS, PERICARDITIS, AND ENDOCARDITIS
I34.81	Nonrheumatic mitral (valve) annulus calcification	257 DISEASES OF MITRAL, TRICUSPID, AND PULMONARY VALVES
I34.89	Other nonrheumatic mitral valve disorders	257 DISEASES OF MITRAL, TRICUSPID, AND PULMONARY VALVES
I47.20	Ventricular tachycardia, unspecified	264 CONGESTIVE HEART FAILURE, CARDIOMYOPATHY, MALIGNANT ARRHYTHMIAS, AND COMPLEX CONGENITAL HEART DISEASE 281 LIFE-THREATENING CARDIAC ARRHYTHMIAS
I47.21	Torsades de pointes	264,281
I47.29	Other ventricular tachycardia	264,281
I71.010	Dissection of ascending aorta	284 DISSECTING OR RUPTURED AORTIC ANEURYSM

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ICD10 Code	Code Description	Recommended Placement
I71.011	Dissection of aortic arch	284 DISSECTING OR RUPTURED AORTIC ANEURYSM
I71.012	Dissection of descending thoracic aorta	284 DISSECTING OR RUPTURED AORTIC ANEURYSM
I71.019	Dissection of thoracic aorta, unspecified	284 DISSECTING OR RUPTURED AORTIC ANEURYSM
I71.10	Thoracic aortic aneurysm, ruptured, unspecified	284 DISSECTING OR RUPTURED AORTIC ANEURYSM
I71.11	Aneurysm of the ascending aorta, ruptured	284 DISSECTING OR RUPTURED AORTIC ANEURYSM
I71.12	Aneurysm of the aortic arch, ruptured	284 DISSECTING OR RUPTURED AORTIC ANEURYSM
I71.13	Aneurysm of the descending thoracic aorta, ruptured	284 DISSECTING OR RUPTURED AORTIC ANEURYSM
I71.20	Thoracic aortic aneurysm, without rupture, unspecified	325 NON-DISSECTING ANEURYSM WITHOUT RUPTURE
I71.21	Aneurysm of the ascending aorta, without rupture	325 NON-DISSECTING ANEURYSM WITHOUT RUPTURE
I71.22	Aneurysm of the aortic arch, without rupture	325 NON-DISSECTING ANEURYSM WITHOUT RUPTURE
I71.23	Aneurysm of the descending thoracic aorta, without rupture	325 NON-DISSECTING ANEURYSM WITHOUT RUPTURE
I71.30	Abdominal aortic aneurysm, ruptured, unspecified	284 DISSECTING OR RUPTURED AORTIC ANEURYSM
I71.31	Pararenal abdominal aortic aneurysm, ruptured	284 DISSECTING OR RUPTURED AORTIC ANEURYSM
I71.32	Juxtarenal abdominal aortic aneurysm, ruptured	284 DISSECTING OR RUPTURED AORTIC ANEURYSM
I71.33	Infrarenal abdominal aortic aneurysm, ruptured	284 DISSECTING OR RUPTURED AORTIC ANEURYSM
I71.40	Abdominal aortic aneurysm, without rupture, unspecified	325 NON-DISSECTING ANEURYSM WITHOUT RUPTURE
I71.41	Pararenal abdominal aortic aneurysm, without rupture	325 NON-DISSECTING ANEURYSM WITHOUT RUPTURE
I71.42	Juxtarenal abdominal aortic aneurysm, without rupture	325 NON-DISSECTING ANEURYSM WITHOUT RUPTURE
I71.43	Infrarenal abdominal aortic aneurysm, without rupture	325 NON-DISSECTING ANEURYSM WITHOUT RUPTURE
I71.50	Thoracoabdominal aortic aneurysm, ruptured, unspecified	284 DISSECTING OR RUPTURED AORTIC ANEURYSM
I71.51	Supraceliac aneurysm of the abdominal aorta, ruptured	284 DISSECTING OR RUPTURED AORTIC ANEURYSM
I71.52	Paravisceral aneurysm of the abdominal aorta, ruptured	284 DISSECTING OR RUPTURED AORTIC ANEURYSM
I71.60	Thoracoabdominal aortic aneurysm, without rupture, unspecified	325 NON-DISSECTING ANEURYSM WITHOUT RUPTURE

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ICD10 Code	Code Description	Recommended Placement
I71.61	Supraceliac aneurysm of the abdominal aorta, without rupture	325 NON-DISSECTING ANEURYSM WITHOUT RUPTURE
I71.62	Paravisceral aneurysm of the abdominal aorta, without rupture	325 NON-DISSECTING ANEURYSM WITHOUT RUPTURE
I77.82	Antineutrophilic cytoplasmic antibody [ANCA] vasculitis	99 END STAGE RENAL DISEASE 129 GRANULOMATOSIS WITH POLYANGIITIS 219 PULMONARY FIBROSIS
J95.87	Transfusion-associated dyspnea (TAD)	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
K76.82	Hepatic encephalopathy	334 ALCOHOLIC FATTY LIVER OR ALCOHOLIC HEPATITIS, CIRRHOSIS OF LIVER
M51.A0	Intervertebral annulus fibrosus defect, lumbar region, unspecified size	402 CONDITIONS OF THE BACK AND SPINE 530 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
M51.A1	Intervertebral annulus fibrosus defect, small, lumbar region	402,530
M51.A2	Intervertebral annulus fibrosus defect, large, lumbar region	402,530
M51.A3	Intervertebral annulus fibrosus defect, lumbosacral region, unspecified size	402 CONDITIONS OF THE BACK AND SPINE 530 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
M51.A4	Intervertebral annulus fibrosus defect, small, lumbosacral region	402,530
M51.A5	Intervertebral annulus fibrosus defect, large, lumbosacral region	402,530
M62.5A0	Muscle wasting and atrophy, not elsewhere classified, back, cervical	292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 377 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
M62.5A1	Muscle wasting and atrophy, not elsewhere classified, back, thoracic	292,377
M62.5A2	Muscle wasting and atrophy, not elsewhere classified, back, lumbosacral	292,377

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ICD10 Code	Code Description	Recommended Placement
M62.5A9	Muscle wasting and atrophy, not elsewhere classified, back, unspecified level	292,377
M93.004	Unspecified slipped upper femoral epiphysis (nontraumatic), bilateral hips	355 CLOSED FRACTURE OF EXTREMITIES (EXCEPT MINOR TOES)
M93.014	Acute slipped upper femoral epiphysis, stable (nontraumatic), bilateral hips	355
M93.024	Chronic slipped upper femoral epiphysis, stable (nontraumatic), bilateral hips	355
M93.034	Acute on chronic slipped upper femoral epiphysis, stable (nontraumatic), bilateral hips	355
M93.041	Acute slipped upper femoral epiphysis, unstable (nontraumatic), right hip	355
M93.042	Acute slipped upper femoral epiphysis, unstable (nontraumatic), left hip	355
M93.043	Acute slipped upper femoral epiphysis, unstable (nontraumatic), unspecified hip	355
M93.044	Acute slipped upper femoral epiphysis, unstable (nontraumatic), bilateral hips	355
M93.051	Acute on chronic slipped upper femoral epiphysis, unstable (nontraumatic), right hip	355
M93.052	Acute on chronic slipped upper femoral epiphysis, unstable (nontraumatic), left hip	355
M93.053	Acute on chronic slipped upper femoral epiphysis, unstable (nontraumatic), unspecified hip	355
M93.054	Acute on chronic slipped upper femoral epiphysis, unstable (nontraumatic), bilateral hips	355
M93.061	Acute slipped upper femoral epiphysis, unspecified stability (nontraumatic), right hip	355
M93.062	Acute slipped upper femoral epiphysis, unspecified stability (nontraumatic), left hip	355
M93.063	Acute slipped upper femoral epiphysis, unspecified stability (nontraumatic), unspecified hip	355
M93.064	Acute slipped upper femoral epiphysis, unspecified stability (nontraumatic), bilateral hips	355

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ICD10 Code	Code Description	Recommended Placement
M93.071	Acute on chronic slipped upper femoral epiphysis, unspecified stability (nontraumatic), right hip	355
M93.072	Acute on chronic slipped upper femoral epiphysis, unspecified stability (nontraumatic), left hip	355
M93.073	Acute on chronic slipped upper femoral epiphysis, unspecified stability (nontraumatic), unspecified hip	355
M93.074	Acute on chronic slipped upper femoral epiphysis, unspecified stability (nontraumatic), bilateral hips	355
M96.A1	Fracture of sternum associated with chest compression and cardiopulmonary resuscitation	490 CLOSED FRACTURES OF RIBS, STERNUM AND COCCYX
M96.A2	Fracture of one rib associated with chest compression and cardiopulmonary resuscitation	490
M96.A3	Multiple fractures of ribs associated with chest compression and cardiopulmonary resuscitation	490
M96.A4	Flail chest associated with chest compression and cardiopulmonary resuscitation	490
M96.A9	Other fracture associated with chest compression and cardiopulmonary resuscitation	490
N14.11	Contrast-induced nephropathy	99 END STAGE RENAL DISEASE 339 CHRONIC KIDNEY DISEASE
N14.19	Nephropathy induced by other drugs, medicaments and biological substances	99,339
N76.82	Fournier disease of vagina and vulva	47 DEEP ABSCESSES, INCLUDING APPENDICITIS AND
N80.00	Endometriosis of the uterus, unspecified	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.01	Superficial endometriosis of the uterus	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.02	Deep endometriosis of the uterus	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.03	Adenomyosis of the uterus	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.101	Endometriosis of right ovary, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.102	Endometriosis of left ovary, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS

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ICD10 Code	Code Description	Recommended Placement
N80.103	Endometriosis of bilateral ovaries, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.109	Endometriosis of ovary, unspecified side, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.111	Superficial endometriosis of right ovary	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.112	Superficial endometriosis of left ovary	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.113	Superficial endometriosis of bilateral ovaries	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.119	Superficial endometriosis of ovary, unspecified ovary	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.121	Deep endometriosis of right ovary	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.122	Deep endometriosis of left ovary	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.123	Deep endometriosis of bilateral ovaries	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.129	Deep endometriosis of ovary, unspecified ovary	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.201	Endometriosis of right fallopian tube, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.202	Endometriosis of left fallopian tube, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.203	Endometriosis of bilateral fallopian tubes, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.209	Endometriosis of unspecified fallopian tube, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.211	Superficial endometriosis of right fallopian tube	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.212	Superficial endometriosis of left fallopian tube	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.213	Superficial endometriosis of bilateral fallopian tubes	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.219	Superficial endometriosis of unspecified fallopian tube	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.221	Deep endometriosis of right fallopian tube	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.222	Deep endometriosis of left fallopian tube	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.223	Deep endometriosis of bilateral fallopian tubes	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.229	Deep endometriosis of unspecified fallopian tube	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.30	Endometriosis of pelvic peritoneum, unspecified	395 ENDOMETRIOSIS AND ADENOMYOSIS

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ICD10 Code	Code Description	Recommended Placement
N80.311	Superficial endometriosis of the anterior cul-de-sac	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.312	Deep endometriosis of the anterior cul-de-sac	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.319	Endometriosis of the anterior cul-de-sac, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.321	Superficial endometriosis of the posterior cul-de-sac	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.322	Deep endometriosis of the posterior cul-de-sac	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.329	Endometriosis of the posterior cul-de-sac, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.331	Superficial endometriosis of the right pelvic sidewall	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.332	Superficial endometriosis of the left pelvic sidewall	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.333	Superficial endometriosis of bilateral pelvic sidewall	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.339	Superficial endometriosis of pelvic sidewall, unspecified side	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.341	Deep endometriosis of the right pelvic sidewall	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.342	Deep endometriosis of the left pelvic sidewall	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.343	Deep endometriosis of the bilateral pelvic sidewall	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.349	Deep endometriosis of the pelvic sidewall, unspecified side	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.351	Endometriosis of the right pelvic sidewall, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.352	Endometriosis of the left pelvic sidewall, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.353	Endometriosis of bilateral pelvic sidewall, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.359	Endometriosis of pelvic sidewall, unspecified side, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.361	Superficial endometriosis of the right pelvic brim	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.362	Superficial endometriosis of the left pelvic brim	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.363	Superficial endometriosis of bilateral pelvic brim	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.369	Superficial endometriosis of the pelvic brim, unspecified side	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.371	Deep endometriosis of the right pelvic brim	395 ENDOMETRIOSIS AND ADENOMYOSIS

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ICD10 Code	Code Description	Recommended Placement
N80.372	Deep endometriosis of the left pelvic brim	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.373	Deep endometriosis of bilateral pelvic brim	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.379	Deep endometriosis of the pelvic brim, unspecified side	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.381	Endometriosis of the right pelvic brim, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.382	Endometriosis of the left pelvic brim, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.383	Endometriosis of bilateral pelvic brim, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.389	Endometriosis of the pelvic brim, unspecified side, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.391	Superficial endometriosis of the pelvic peritoneum, other specified sites	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.392	Deep endometriosis of the pelvic peritoneum, other specified sites	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.399	Endometriosis of the pelvic peritoneum, other specified sites, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.3A1	Superficial endometriosis of the right uterosacral ligament	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.3A2	Superficial endometriosis of the left uterosacral ligament	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.3A3	Superficial endometriosis of the bilateral uterosacral ligament(s)	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.3A9	Superficial endometriosis of the uterosacral ligament(s), unspecified side	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.3B1	Deep endometriosis of the right uterosacral ligament	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.3B2	Deep endometriosis of the left uterosacral ligament	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.3B3	Deep endometriosis of bilateral uterosacral ligament(s)	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.3B9	Deep endometriosis of the uterosacral ligament(s), unspecified side	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.3C1	Endometriosis of the right uterosacral ligament, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.3C2	Endometriosis of the left uterosacral ligament, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.3C3	Endometriosis of bilateral uterosacral ligament(s), unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.3C9	Endometriosis of the uterosacral ligament(s), unspecified side, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS

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ICD10 Code	Code Description	Recommended Placement
N80.40	Endometriosis of rectovaginal septum, unspecified involvement of vagina	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.41	Endometriosis of rectovaginal septum without involvement of vagina	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.42	Endometriosis of rectovaginal septum with involvement of vagina	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.50	Endometriosis of intestine, unspecified	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.511	Superficial endometriosis of the rectum	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.512	Deep endometriosis of the rectum	41 INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.519	Endometriosis of the rectum, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.521	Superficial endometriosis of the sigmoid colon	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.522	Deep endometriosis of the sigmoid colon	41 INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.529	Endometriosis of the sigmoid colon, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.531	Superficial endometriosis of the cecum	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.532	Deep endometriosis of the cecum	41 INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.539	Endometriosis of the cecum, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.541	Superficial endometriosis of the appendix	395 ENDOMETRIOSIS AND ADENOMYOSIS

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ICD10 Code	Code Description	Recommended Placement
N80.542	Deep endometriosis of the appendix	41 INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.549	Endometriosis of the appendix, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.551	Superficial endometriosis of other parts of the colon	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.552	Deep endometriosis of other parts of the colon	41 INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.559	Endometriosis of other parts of the colon, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.561	Superficial endometriosis of the small intestine	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.562	Deep endometriosis of the small intestine	41 INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.569	Endometriosis of the small intestine, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.A0	Endometriosis of bladder, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.A1	Superficial endometriosis of bladder	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.A2	Deep endometriosis of bladder	327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION 395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.A41	Superficial endometriosis of right ureter	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.A42	Superficial endometriosis of left ureter	395 ENDOMETRIOSIS AND ADENOMYOSIS

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ICD10 Code	Code Description	Recommended Placement
N80.A43	Superficial endometriosis of bilateral ureters	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.A49	Superficial endometriosis of unspecified ureter	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.A51	Deep endometriosis of right ureter	327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION 395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.A52	Deep endometriosis of left ureter	327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION 395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.A53	Deep endometriosis of bilateral ureters	327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION 395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.A59	Deep endometriosis of unspecified ureter	327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION 395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.A61	Endometriosis of right ureter, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.A62	Endometriosis of left ureter, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.A63	Endometriosis of bilateral ureters, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.A69	Endometriosis of unspecified ureter, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.B1	Endometriosis of pleura	372 BENIGN NEOPLASM OF RESPIRATORY AND INTRATHORACIC ORGANS 395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.B2	Endometriosis of lung	372 BENIGN NEOPLASM OF RESPIRATORY AND INTRATHORACIC ORGANS 395 ENDOMETRIOSIS AND ADENOMYOSIS

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ICD10 Code	Code Description	Recommended Placement
N80.B31	Superficial endometriosis of diaphragm	372 BENIGN NEOPLASM OF RESPIRATORY AND INTRATHORACIC ORGANS 395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.B32	Deep endometriosis of diaphragm	372 BENIGN NEOPLASM OF RESPIRATORY AND INTRATHORACIC ORGANS 395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.B39	Endometriosis of diaphragm, unspecified depth	372 BENIGN NEOPLASM OF RESPIRATORY AND INTRATHORACIC ORGANS 395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.B4	Endometriosis of the pericardial space	372 BENIGN NEOPLASM OF RESPIRATORY AND INTRATHORACIC ORGANS 395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.B5	Endometriosis of the mediastinal space	372 BENIGN NEOPLASM OF RESPIRATORY AND INTRATHORACIC ORGANS 395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.B6	Endometriosis of cardiothoracic space	372 BENIGN NEOPLASM OF RESPIRATORY AND INTRATHORACIC ORGANS 395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.C0	Endometriosis of the abdomen, unspecified	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.C10	Endometriosis of the anterior abdominal wall, subcutaneous tissue	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.C11	Endometriosis of the anterior abdominal wall, fascia and muscular layers	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.C19	Endometriosis of the anterior abdominal wall, unspecified depth	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.C2	Endometriosis of the umbilicus	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.C3	Endometriosis of the inguinal canal	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.C4	Endometriosis of extra-pelvic abdominal peritoneum	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.C9	Endometriosis of other site of abdomen	395 ENDOMETRIOSIS AND ADENOMYOSIS

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ICD10 Code	Code Description	Recommended Placement
N80.D0	Endometriosis of the pelvic nerves, unspecified	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.D1	Endometriosis of the sacral splanchnic nerves	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.D2	Endometriosis of the sacral nerve roots	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.D3	Endometriosis of the obturator nerve	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.D4	Endometriosis of the sciatic nerve	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.D5	Endometriosis of the pudendal nerve	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.D6	Endometriosis of the femoral nerve	395 ENDOMETRIOSIS AND ADENOMYOSIS
N80.D9	Endometriosis of other pelvic nerve	395 ENDOMETRIOSIS AND ADENOMYOSIS
N85.A	Isthmocele	423 MENSTRUAL BLEEDING DISORDERS
O35.00X0	Maternal care for (suspected) central nervous system malformation or damage in fetus, unspecified, not applicable or unspecified	1 PREGNANCY
O35.00X1	Maternal care for (suspected) central nervous system malformation or damage in fetus, unspecified, fetus 1	1 PREGNANCY
O35.00X2	Maternal care for (suspected) central nervous system malformation or damage in fetus, unspecified, fetus 2	1 PREGNANCY
O35.00X3	Maternal care for (suspected) central nervous system malformation or damage in fetus, unspecified, fetus 3	1 PREGNANCY
O35.00X4	Maternal care for (suspected) central nervous system malformation or damage in fetus, unspecified, fetus 4	1 PREGNANCY
O35.00X5	Maternal care for (suspected) central nervous system malformation or damage in fetus, unspecified, fetus 5	1 PREGNANCY
O35.00X9	Maternal care for (suspected) central nervous system malformation or damage in fetus, unspecified, other fetus	1 PREGNANCY
O35.01X0	Maternal care for (suspected) central nervous system malformation or damage in fetus, agenesis of the corpus callosum, not applicable or unspecified	1 PREGNANCY

Appendix B
New Codes

ICD10 Code	Code Description	Recommended Placement
O35.01X1	Maternal care for (suspected) central nervous system malformation or damage in fetus, agenesis of the corpus callosum, fetus 1	1 PREGNANCY
O35.01X2	Maternal care for (suspected) central nervous system malformation or damage in fetus, agenesis of the corpus callosum, fetus 2	1 PREGNANCY
O35.01X3	Maternal care for (suspected) central nervous system malformation or damage in fetus, agenesis of the corpus callosum, fetus 3	1 PREGNANCY
O35.01X4	Maternal care for (suspected) central nervous system malformation or damage in fetus, agenesis of the corpus callosum, fetus 4	1 PREGNANCY
O35.01X5	Maternal care for (suspected) central nervous system malformation or damage in fetus, agenesis of the corpus callosum, fetus 5	1 PREGNANCY
O35.01X9	Maternal care for (suspected) central nervous system malformation or damage in fetus, agenesis of the corpus callosum, other fetus	1 PREGNANCY
O35.02X0	Maternal care for (suspected) central nervous system malformation or damage in fetus, anencephaly, not applicable or unspecified	1 PREGNANCY
O35.02X1	Maternal care for (suspected) central nervous system malformation or damage in fetus, anencephaly, fetus 1	1 PREGNANCY
O35.02X2	Maternal care for (suspected) central nervous system malformation or damage in fetus, anencephaly, fetus 2	1 PREGNANCY
O35.02X3	Maternal care for (suspected) central nervous system malformation or damage in fetus, anencephaly, fetus 3	1 PREGNANCY
O35.02X4	Maternal care for (suspected) central nervous system malformation or damage in fetus, anencephaly, fetus 4	1 PREGNANCY
O35.02X5	Maternal care for (suspected) central nervous system malformation or damage in fetus, anencephaly, fetus 5	1 PREGNANCY
O35.02X9	Maternal care for (suspected) central nervous system malformation or damage in fetus, anencephaly, other fetus	1 PREGNANCY

Appendix B
New Codes

ICD10 Code	Code Description	Recommended Placement
O35.03X0	Maternal care for (suspected) central nervous system malformation or damage in fetus, choroid plexus cysts, not applicable or unspecified	1 PREGNANCY
O35.03X1	Maternal care for (suspected) central nervous system malformation or damage in fetus, choroid plexus cysts, fetus 1	1 PREGNANCY
O35.03X2	Maternal care for (suspected) central nervous system malformation or damage in fetus, choroid plexus cysts, fetus 2	1 PREGNANCY
O35.03X3	Maternal care for (suspected) central nervous system malformation or damage in fetus, choroid plexus cysts, fetus 3	1 PREGNANCY
O35.03X4	Maternal care for (suspected) central nervous system malformation or damage in fetus, choroid plexus cysts, fetus 4	1 PREGNANCY
O35.03X5	Maternal care for (suspected) central nervous system malformation or damage in fetus, choroid plexus cysts, fetus 5	1 PREGNANCY
O35.03X9	Maternal care for (suspected) central nervous system malformation or damage in fetus, choroid plexus cysts, other fetus	1 PREGNANCY
O35.04X0	Maternal care for (suspected) central nervous system malformation or damage in fetus, encephalocele, not applicable or unspecified	1 PREGNANCY
O35.04X1	Maternal care for (suspected) central nervous system malformation or damage in fetus, encephalocele, fetus 1	1 PREGNANCY
O35.04X2	Maternal care for (suspected) central nervous system malformation or damage in fetus, encephalocele, fetus 2	1 PREGNANCY
O35.04X3	Maternal care for (suspected) central nervous system malformation or damage in fetus, encephalocele, fetus 3	1 PREGNANCY
O35.04X4	Maternal care for (suspected) central nervous system malformation or damage in fetus, encephalocele, fetus 4	1 PREGNANCY
O35.04X5	Maternal care for (suspected) central nervous system malformation or damage in fetus, encephalocele, fetus 5	1 PREGNANCY
O35.04X9	Maternal care for (suspected) central nervous system malformation or damage in fetus, encephalocele, other fetus	1 PREGNANCY

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New Codes

ICD10 Code	Code Description	Recommended Placement
O35.05X0	Maternal care for (suspected) central nervous system malformation or damage in fetus, holoprosencephaly, not applicable or unspecified	1 PREGNANCY
O35.05X1	Maternal care for (suspected) central nervous system malformation or damage in fetus, holoprosencephaly, fetus 1	1 PREGNANCY
O35.05X2	Maternal care for (suspected) central nervous system malformation or damage in fetus, holoprosencephaly, fetus 2	1 PREGNANCY
O35.05X3	Maternal care for (suspected) central nervous system malformation or damage in fetus, holoprosencephaly, fetus 3	1 PREGNANCY
O35.05X4	Maternal care for (suspected) central nervous system malformation or damage in fetus, holoprosencephaly, fetus 4	1 PREGNANCY
O35.05X5	Maternal care for (suspected) central nervous system malformation or damage in fetus, holoprosencephaly, fetus 5	1 PREGNANCY
O35.05X9	Maternal care for (suspected) central nervous system malformation or damage in fetus, holoprosencephaly, other fetus	1 PREGNANCY
O35.06X0	Maternal care for (suspected) central nervous system malformation or damage in fetus, hydrocephaly, not applicable or unspecified	1 PREGNANCY
O35.06X1	Maternal care for (suspected) central nervous system malformation or damage in fetus, hydrocephaly, fetus 1	1 PREGNANCY
O35.06X2	Maternal care for (suspected) central nervous system malformation or damage in fetus, hydrocephaly, fetus 2	1 PREGNANCY
O35.06X3	Maternal care for (suspected) central nervous system malformation or damage in fetus, hydrocephaly, fetus 3	1 PREGNANCY
O35.06X4	Maternal care for (suspected) central nervous system malformation or damage in fetus, hydrocephaly, fetus 4	1 PREGNANCY
O35.06X5	Maternal care for (suspected) central nervous system malformation or damage in fetus, hydrocephaly, fetus 5	1 PREGNANCY
O35.06X9	Maternal care for (suspected) central nervous system malformation or damage in fetus, hydrocephaly, other fetus	1 PREGNANCY

Appendix B
New Codes

ICD10 Code	Code Description	Recommended Placement
O35.07X0	Maternal care for (suspected) central nervous system malformation or damage in fetus, microcephaly, not applicable or unspecified	1 PREGNANCY
O35.07X1	Maternal care for (suspected) central nervous system malformation or damage in fetus, microcephaly, fetus 1	1 PREGNANCY
O35.07X2	Maternal care for (suspected) central nervous system malformation or damage in fetus, microcephaly, fetus 2	1 PREGNANCY
O35.07X3	Maternal care for (suspected) central nervous system malformation or damage in fetus, microcephaly, fetus 3	1 PREGNANCY
O35.07X4	Maternal care for (suspected) central nervous system malformation or damage in fetus, microcephaly, fetus 4	1 PREGNANCY
O35.07X5	Maternal care for (suspected) central nervous system malformation or damage in fetus, microcephaly, fetus 5	1 PREGNANCY
O35.07X9	Maternal care for (suspected) central nervous system malformation or damage in fetus, microcephaly, other fetus	1 PREGNANCY
O35.08X0	Maternal care for (suspected) central nervous system malformation or damage in fetus, spina bifida, not applicable or unspecified	1 PREGNANCY
O35.08X1	Maternal care for (suspected) central nervous system malformation or damage in fetus, spina bifida, fetus 1	1 PREGNANCY
O35.08X2	Maternal care for (suspected) central nervous system malformation or damage in fetus, spina bifida, fetus 2	1 PREGNANCY
O35.08X3	Maternal care for (suspected) central nervous system malformation or damage in fetus, spina bifida, fetus 3	1 PREGNANCY
O35.08X4	Maternal care for (suspected) central nervous system malformation or damage in fetus, spina bifida, fetus 4	1 PREGNANCY
O35.08X5	Maternal care for (suspected) central nervous system malformation or damage in fetus, spina bifida, fetus 5	1 PREGNANCY
O35.08X9	Maternal care for (suspected) central nervous system malformation or damage in fetus, spina bifida, other fetus	1 PREGNANCY

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New Codes

ICD10 Code	Code Description	Recommended Placement
O35.09X0	Maternal care for (suspected) other central nervous system malformation or damage in fetus, not applicable or unspecified	1 PREGNANCY
O35.09X1	Maternal care for (suspected) other central nervous system malformation or damage in fetus, fetus 1	1 PREGNANCY
O35.09X2	Maternal care for (suspected) other central nervous system malformation or damage in fetus, fetus 2	1 PREGNANCY
O35.09X3	Maternal care for (suspected) other central nervous system malformation or damage in fetus, fetus 3	1 PREGNANCY
O35.09X4	Maternal care for (suspected) other central nervous system malformation or damage in fetus, fetus 4	1 PREGNANCY
O35.09X5	Maternal care for (suspected) other central nervous system malformation or damage in fetus, fetus 5	1 PREGNANCY
O35.09X9	Maternal care for (suspected) other central nervous system malformation or damage in fetus, other fetus	1 PREGNANCY
O35.10X0	Maternal care for (suspected) chromosomal abnormality in fetus, unspecified, not applicable or unspecified	1 PREGNANCY
O35.10X1	Maternal care for (suspected) chromosomal abnormality in fetus, unspecified, fetus 1	1 PREGNANCY
O35.10X2	Maternal care for (suspected) chromosomal abnormality in fetus, unspecified, fetus 2	1 PREGNANCY
O35.10X3	Maternal care for (suspected) chromosomal abnormality in fetus, unspecified, fetus 3	1 PREGNANCY
O35.10X4	Maternal care for (suspected) chromosomal abnormality in fetus, unspecified, fetus 4	1 PREGNANCY
O35.10X5	Maternal care for (suspected) chromosomal abnormality in fetus, unspecified, fetus 5	1 PREGNANCY
O35.10X9	Maternal care for (suspected) chromosomal abnormality in fetus, unspecified, other fetus	1 PREGNANCY
O35.11X0	Maternal care for (suspected) chromosomal abnormality in fetus, Trisomy 13, not applicable or unspecified	1 PREGNANCY

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New Codes

ICD10 Code	Code Description	Recommended Placement
O35.11X1	Maternal care for (suspected) chromosomal abnormality in fetus, Trisomy 13, fetus 1	1 PREGNANCY
O35.11X2	Maternal care for (suspected) chromosomal abnormality in fetus, Trisomy 13, fetus 2	1 PREGNANCY
O35.11X3	Maternal care for (suspected) chromosomal abnormality in fetus, Trisomy 13, fetus 3	1 PREGNANCY
O35.11X4	Maternal care for (suspected) chromosomal abnormality in fetus, Trisomy 13, fetus 4	1 PREGNANCY
O35.11X5	Maternal care for (suspected) chromosomal abnormality in fetus, Trisomy 13, fetus 5	1 PREGNANCY
O35.11X9	Maternal care for (suspected) chromosomal abnormality in fetus, Trisomy 13, other fetus	1 PREGNANCY
O35.12X0	Maternal care for (suspected) chromosomal abnormality in fetus, Trisomy 18, not applicable or unspecified	1 PREGNANCY
O35.12X1	Maternal care for (suspected) chromosomal abnormality in fetus, Trisomy 18, fetus 1	1 PREGNANCY
O35.12X2	Maternal care for (suspected) chromosomal abnormality in fetus, Trisomy 18, fetus 2	1 PREGNANCY
O35.12X3	Maternal care for (suspected) chromosomal abnormality in fetus, Trisomy 18, fetus 3	1 PREGNANCY
O35.12X4	Maternal care for (suspected) chromosomal abnormality in fetus, Trisomy 18, fetus 4	1 PREGNANCY
O35.12X5	Maternal care for (suspected) chromosomal abnormality in fetus, Trisomy 18, fetus 5	1 PREGNANCY
O35.12X9	Maternal care for (suspected) chromosomal abnormality in fetus, Trisomy 18, other fetus	1 PREGNANCY
O35.13X0	Maternal care for (suspected) chromosomal abnormality in fetus, Trisomy 21, not applicable or unspecified	1 PREGNANCY
O35.13X1	Maternal care for (suspected) chromosomal abnormality in fetus, Trisomy 21, fetus 1	1 PREGNANCY

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New Codes

ICD10 Code	Code Description	Recommended Placement
O35.13X2	Maternal care for (suspected) chromosomal abnormality in fetus, Trisomy 21, fetus 2	1 PREGNANCY
O35.13X3	Maternal care for (suspected) chromosomal abnormality in fetus, Trisomy 21, fetus 3	1 PREGNANCY
O35.13X4	Maternal care for (suspected) chromosomal abnormality in fetus, Trisomy 21, fetus 4	1 PREGNANCY
O35.13X5	Maternal care for (suspected) chromosomal abnormality in fetus, Trisomy 21, fetus 5	1 PREGNANCY
O35.13X9	Maternal care for (suspected) chromosomal abnormality in fetus, Trisomy 21, other fetus	1 PREGNANCY
O35.14X0	Maternal care for (suspected) chromosomal abnormality in fetus, Turner Syndrome, not applicable or unspecified	1 PREGNANCY
O35.14X1	Maternal care for (suspected) chromosomal abnormality in fetus, Turner Syndrome, fetus 1	1 PREGNANCY
O35.14X2	Maternal care for (suspected) chromosomal abnormality in fetus, Turner Syndrome, fetus 2	1 PREGNANCY
O35.14X3	Maternal care for (suspected) chromosomal abnormality in fetus, Turner Syndrome, fetus 3	1 PREGNANCY
O35.14X4	Maternal care for (suspected) chromosomal abnormality in fetus, Turner Syndrome, fetus 4	1 PREGNANCY
O35.14X5	Maternal care for (suspected) chromosomal abnormality in fetus, Turner Syndrome, fetus 5	1 PREGNANCY
O35.14X9	Maternal care for (suspected) chromosomal abnormality in fetus, Turner Syndrome, other fetus	1 PREGNANCY
O35.15X0	Maternal care for (suspected) chromosomal abnormality in fetus, sex chromosome abnormality, not applicable or unspecified	1 PREGNANCY
O35.15X1	Maternal care for (suspected) chromosomal abnormality in fetus, sex chromosome abnormality, fetus 1	1 PREGNANCY
O35.15X2	Maternal care for (suspected) chromosomal abnormality in fetus, sex chromosome abnormality, fetus 2	1 PREGNANCY

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New Codes

ICD10 Code	Code Description	Recommended Placement
O35.15X3	Maternal care for (suspected) chromosomal abnormality in fetus, sex chromosome abnormality, fetus 3	1 PREGNANCY
O35.15X4	Maternal care for (suspected) chromosomal abnormality in fetus, sex chromosome abnormality, fetus 4	1 PREGNANCY
O35.15X5	Maternal care for (suspected) chromosomal abnormality in fetus, sex chromosome abnormality, fetus 5	1 PREGNANCY
O35.15X9	Maternal care for (suspected) chromosomal abnormality in fetus, sex chromosome abnormality, other fetus	1 PREGNANCY
O35.19X0	Maternal care for (suspected) chromosomal abnormality in fetus, other chromosomal abnormality, not applicable or unspecified	1 PREGNANCY
O35.19X1	Maternal care for (suspected) chromosomal abnormality in fetus, other chromosomal abnormality, fetus 1	1 PREGNANCY
O35.19X2	Maternal care for (suspected) chromosomal abnormality in fetus, other chromosomal abnormality, fetus 2	1 PREGNANCY
O35.19X3	Maternal care for (suspected) chromosomal abnormality in fetus, other chromosomal abnormality, fetus 3	1 PREGNANCY
O35.19X4	Maternal care for (suspected) chromosomal abnormality in fetus, other chromosomal abnormality, fetus 4	1 PREGNANCY
O35.19X5	Maternal care for (suspected) chromosomal abnormality in fetus, other chromosomal abnormality, fetus 5	1 PREGNANCY
O35.19X9	Maternal care for (suspected) chromosomal abnormality in fetus, other chromosomal abnormality, other fetus	1 PREGNANCY
O35.AXX0	Maternal care for other (suspected) fetal abnormality and damage, fetal facial anomalies, not applicable or unspecified	1 PREGNANCY
O35.AXX1	Maternal care for other (suspected) fetal abnormality and damage, fetal facial anomalies, fetus 1	1 PREGNANCY
O35.AXX2	Maternal care for other (suspected) fetal abnormality and damage, fetal facial anomalies, fetus 2	1 PREGNANCY
O35.AXX3	Maternal care for other (suspected) fetal abnormality and damage, fetal facial anomalies, fetus 3	1 PREGNANCY

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New Codes

ICD10 Code	Code Description	Recommended Placement
O35.AXX4	Maternal care for other (suspected) fetal abnormality and damage, fetal facial anomalies, fetus 4	1 PREGNANCY
O35.AXX5	Maternal care for other (suspected) fetal abnormality and damage, fetal facial anomalies, fetus 5	1 PREGNANCY
O35.AXX9	Maternal care for other (suspected) fetal abnormality and damage, fetal facial anomalies, other fetus	1 PREGNANCY
O35.BXX0	Maternal care for other (suspected) fetal abnormality and damage, fetal cardiac anomalies, not applicable or unspecified	1 PREGNANCY
O35.BXX1	Maternal care for other (suspected) fetal abnormality and damage, fetal cardiac anomalies, fetus 1	1 PREGNANCY
O35.BXX2	Maternal care for other (suspected) fetal abnormality and damage, fetal cardiac anomalies, fetus 2	1 PREGNANCY
O35.BXX3	Maternal care for other (suspected) fetal abnormality and damage, fetal cardiac anomalies, fetus 3	1 PREGNANCY
O35.BXX4	Maternal care for other (suspected) fetal abnormality and damage, fetal cardiac anomalies, fetus 4	1 PREGNANCY
O35.BXX5	Maternal care for other (suspected) fetal abnormality and damage, fetal cardiac anomalies, fetus 5	1 PREGNANCY
O35.BXX9	Maternal care for other (suspected) fetal abnormality and damage, fetal cardiac anomalies, other fetus	1 PREGNANCY
O35.CXX0	Maternal care for other (suspected) fetal abnormality and damage, fetal pulmonary anomalies, not applicable or unspecified	1 PREGNANCY
O35.CXX1	Maternal care for other (suspected) fetal abnormality and damage, fetal pulmonary anomalies, fetus 1	1 PREGNANCY
O35.CXX2	Maternal care for other (suspected) fetal abnormality and damage, fetal pulmonary anomalies, fetus 2	1 PREGNANCY
O35.CXX3	Maternal care for other (suspected) fetal abnormality and damage, fetal pulmonary anomalies, fetus 3	1 PREGNANCY
O35.CXX4	Maternal care for other (suspected) fetal abnormality and damage, fetal pulmonary anomalies, fetus 4	1 PREGNANCY

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New Codes

ICD10 Code	Code Description	Recommended Placement
O35.CXX5	Maternal care for other (suspected) fetal abnormality and damage, fetal pulmonary anomalies, fetus 5	1 PREGNANCY
O35.CXX9	Maternal care for other (suspected) fetal abnormality and damage, fetal pulmonary anomalies, other fetus	1 PREGNANCY
O35.DXX0	Maternal care for other (suspected) fetal abnormality and damage, fetal gastrointestinal anomalies, not applicable or unspecified	1 PREGNANCY
O35.DXX1	Maternal care for other (suspected) fetal abnormality and damage, fetal gastrointestinal anomalies, fetus 1	1 PREGNANCY
O35.DXX2	Maternal care for other (suspected) fetal abnormality and damage, fetal gastrointestinal anomalies, fetus 2	1 PREGNANCY
O35.DXX3	Maternal care for other (suspected) fetal abnormality and damage, fetal gastrointestinal anomalies, fetus 3	1 PREGNANCY
O35.DXX4	Maternal care for other (suspected) fetal abnormality and damage, fetal gastrointestinal anomalies, fetus 4	1 PREGNANCY
O35.DXX5	Maternal care for other (suspected) fetal abnormality and damage, fetal gastrointestinal anomalies, fetus 5	1 PREGNANCY
O35.DXX9	Maternal care for other (suspected) fetal abnormality and damage, fetal gastrointestinal anomalies, other fetus	1 PREGNANCY
O35.EXX0	Maternal care for other (suspected) fetal abnormality and damage, fetal genitourinary anomalies, not applicable or unspecified	1 PREGNANCY
O35.EXX1	Maternal care for other (suspected) fetal abnormality and damage, fetal genitourinary anomalies, fetus 1	1 PREGNANCY
O35.EXX2	Maternal care for other (suspected) fetal abnormality and damage, fetal genitourinary anomalies, fetus 2	1 PREGNANCY
O35.EXX3	Maternal care for other (suspected) fetal abnormality and damage, fetal genitourinary anomalies, fetus 3	1 PREGNANCY
O35.EXX4	Maternal care for other (suspected) fetal abnormality and damage, fetal genitourinary anomalies, fetus 4	1 PREGNANCY

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New Codes

ICD10 Code	Code Description	Recommended Placement
O35.EXX5	Maternal care for other (suspected) fetal abnormality and damage, fetal genitourinary anomalies, fetus 5	1 PREGNANCY
O35.EXX9	Maternal care for other (suspected) fetal abnormality and damage, fetal genitourinary anomalies, other fetus	1 PREGNANCY
O35.FXX0	Maternal care for other (suspected) fetal abnormality and damage, fetal musculoskeletal anomalies of trunk, not applicable or unspecified	1 PREGNANCY
O35.FXX1	Maternal care for other (suspected) fetal abnormality and damage, fetal musculoskeletal anomalies of trunk, fetus 1	1 PREGNANCY
O35.FXX2	Maternal care for other (suspected) fetal abnormality and damage, fetal musculoskeletal anomalies of trunk, fetus 2	1 PREGNANCY
O35.FXX3	Maternal care for other (suspected) fetal abnormality and damage, fetal musculoskeletal anomalies of trunk, fetus 3	1 PREGNANCY
O35.FXX4	Maternal care for other (suspected) fetal abnormality and damage, fetal musculoskeletal anomalies of trunk, fetus 4	1 PREGNANCY
O35.FXX5	Maternal care for other (suspected) fetal abnormality and damage, fetal musculoskeletal anomalies of trunk, fetus 5	1 PREGNANCY
O35.FXX9	Maternal care for other (suspected) fetal abnormality and damage, fetal musculoskeletal anomalies of trunk, other fetus	1 PREGNANCY
O35.GXX0	Maternal care for other (suspected) fetal abnormality and damage, fetal upper extremities anomalies, not applicable or unspecified	1 PREGNANCY
O35.GXX1	Maternal care for other (suspected) fetal abnormality and damage, fetal upper extremities anomalies, fetus 1	1 PREGNANCY
O35.GXX2	Maternal care for other (suspected) fetal abnormality and damage, fetal upper extremities anomalies, fetus 2	1 PREGNANCY

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New Codes

ICD10 Code	Code Description	Recommended Placement
O35.GXX3	Maternal care for other (suspected) fetal abnormality and damage, fetal upper extremities anomalies, fetus 3	1 PREGNANCY
O35.GXX4	Maternal care for other (suspected) fetal abnormality and damage, fetal upper extremities anomalies, fetus 4	1 PREGNANCY
O35.GXX5	Maternal care for other (suspected) fetal abnormality and damage, fetal upper extremities anomalies, fetus 5	1 PREGNANCY
O35.GXX9	Maternal care for other (suspected) fetal abnormality and damage, fetal upper extremities anomalies, other fetus	1 PREGNANCY
O35.HXX0	Maternal care for other (suspected) fetal abnormality and damage, fetal lower extremities anomalies, not applicable or unspecified	1 PREGNANCY
O35.HXX1	Maternal care for other (suspected) fetal abnormality and damage, fetal lower extremities anomalies, fetus 1	1 PREGNANCY
O35.HXX2	Maternal care for other (suspected) fetal abnormality and damage, fetal lower extremities anomalies, fetus 2	1 PREGNANCY
O35.HXX3	Maternal care for other (suspected) fetal abnormality and damage, fetal lower extremities anomalies, fetus 3	1 PREGNANCY
O35.HXX4	Maternal care for other (suspected) fetal abnormality and damage, fetal lower extremities anomalies, fetus 4	1 PREGNANCY
O35.HXX5	Maternal care for other (suspected) fetal abnormality and damage, fetal lower extremities anomalies, fetus 5	1 PREGNANCY
O35.HXX9	Maternal care for other (suspected) fetal abnormality and damage, fetal lower extremities anomalies, other fetus	1 PREGNANCY
P28.30	Primary sleep apnea of newborn, unspecified	11 RESPIRATORY CONDITIONS OF FETUS AND NEWBORN
P28.31	Primary central sleep apnea of newborn	11 RESPIRATORY CONDITIONS OF FETUS AND NEWBORN
P28.32	Primary obstructive sleep apnea of newborn	11 RESPIRATORY CONDITIONS OF FETUS AND NEWBORN
P28.33	Primary mixed sleep apnea of newborn	11 RESPIRATORY CONDITIONS OF FETUS AND NEWBORN
P28.39	Other primary sleep apnea of newborn	11 RESPIRATORY CONDITIONS OF FETUS AND NEWBORN
P28.40	Unspecified apnea of newborn	11 RESPIRATORY CONDITIONS OF FETUS AND NEWBORN

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ICD10 Code	Code Description	Recommended Placement
P28.41	Central neonatal apnea of newborn	11 RESPIRATORY CONDITIONS OF FETUS AND NEWBORN
P28.42	Obstructive apnea of newborn	11 RESPIRATORY CONDITIONS OF FETUS AND NEWBORN
P28.43	Mixed neonatal apnea of newborn	11 RESPIRATORY CONDITIONS OF FETUS AND NEWBORN
P28.49	Other apnea of newborn	11 RESPIRATORY CONDITIONS OF FETUS AND NEWBORN
Q21.10	Atrial septal defect, unspecified	118 ATRIAL SEPTAL DEFECT, SECUNDUM
Q21.11	Secundum atrial septal defect	118 ATRIAL SEPTAL DEFECT, SECUNDUM
Q21.12	Patent foramen ovale	118 ATRIAL SEPTAL DEFECT, SECUNDUM
Q21.13	Coronary sinus atrial septal defect	118 ATRIAL SEPTAL DEFECT, SECUNDUM
Q21.14	Superior sinus venosus atrial septal defect	118 ATRIAL SEPTAL DEFECT, SECUNDUM
Q21.15	Inferior sinus venosus atrial septal defect	118 ATRIAL SEPTAL DEFECT, SECUNDUM
Q21.16	Sinus venosus atrial septal defect, unspecified	118 ATRIAL SEPTAL DEFECT, SECUNDUM
Q21.19	Other specified atrial septal defect	118 ATRIAL SEPTAL DEFECT, SECUNDUM
Q21.20	Atrioventricular septal defect, unspecified as to partial or complete	84 ENDOCARDIAL CUSHION DEFECTS
Q21.21	Partial atrioventricular septal defect	84 ENDOCARDIAL CUSHION DEFECTS
Q21.22	Transitional atrioventricular septal defect	84 ENDOCARDIAL CUSHION DEFECTS
Q21.23	Complete atrioventricular septal defect	84 ENDOCARDIAL CUSHION DEFECTS
Q85.81	PTEN tumor syndrome	191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER
Q85.82	Other Cowden syndrome	191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER
Q85.83	Von Hippel-Lindau syndrome	125 BENIGN NEOPLASM OF THE BRAIN AND SPINAL CORD
Q85.89	Other phakomatoses, not elsewhere classified	125 BENIGN NEOPLASM OF THE BRAIN AND SPINAL CORD
S06.0XAA	Concussion with loss of consciousness status unknown, initial encounter	91 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS
S06.0XAD	Concussion with loss of consciousness status unknown, subsequent encounter	91 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS
S06.0XAS	Concussion with loss of consciousness status unknown, sequela	91 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS

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ICD10 Code	Code Description	Recommended Placement
S06.1XAA	Traumatic cerebral edema with loss of consciousness status unknown, initial encounter	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
S06.1XAD	Traumatic cerebral edema with loss of consciousness status unknown, subsequent encounter	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
S06.1XAS	Traumatic cerebral edema with loss of consciousness status unknown, sequela	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
S06.2XAA	Diffuse traumatic brain injury with loss of consciousness status unknown, initial encounter	91 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS
S06.2XAD	Diffuse traumatic brain injury with loss of consciousness status unknown, subsequent encounter	91 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS
S06.2XAS	Diffuse traumatic brain injury with loss of consciousness status unknown, sequela	91 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS
S06.30AA	Unspecified focal traumatic brain injury with loss of consciousness status unknown, initial encounter	91 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS
S06.30AD	Unspecified focal traumatic brain injury with loss of consciousness status unknown, subsequent encounter	91 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS
S06.30AS	Unspecified focal traumatic brain injury with loss of consciousness status unknown, sequela	91 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS
S06.31AA	Contusion and laceration of right cerebrum with loss of consciousness status unknown, initial encounter	91 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS
S06.31AD	Contusion and laceration of right cerebrum with loss of consciousness status unknown, subsequent encounter	91 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS
S06.31AS	Contusion and laceration of right cerebrum with loss of consciousness status unknown, sequela	91 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS
S06.32AA	Contusion and laceration of left cerebrum with loss of consciousness status unknown, initial encounter	91 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS

Appendix B
New Codes

ICD10 Code	Code Description	Recommended Placement
S06.32AD	Contusion and laceration of left cerebrum with loss of consciousness status unknown, subsequent encounter	91 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS
S06.32AS	Contusion and laceration of left cerebrum with loss of consciousness status unknown, sequela	91 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS
S06.33AA	Contusion and laceration of cerebrum, unspecified, with loss of consciousness status unknown, initial encounter	91 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS
S06.33AD	Contusion and laceration of cerebrum, unspecified, with loss of consciousness status unknown, subsequent encounter	91 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS
S06.33AS	Contusion and laceration of cerebrum, unspecified, with loss of consciousness status unknown, sequela	91 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS
S06.34AA	Traumatic hemorrhage of right cerebrum with loss of consciousness status unknown, initial encounter	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
S06.34AD	Traumatic hemorrhage of right cerebrum with loss of consciousness status unknown, subsequent encounter	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
S06.34AS	Traumatic hemorrhage of right cerebrum with loss of consciousness status unknown, sequela	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
S06.35AA	Traumatic hemorrhage of left cerebrum with loss of consciousness status unknown, initial encounter	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
S06.35AD	Traumatic hemorrhage of left cerebrum with loss of consciousness status unknown, subsequent encounter	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
S06.35AS	Traumatic hemorrhage of left cerebrum with loss of consciousness status unknown, sequela	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN

Appendix B
New Codes

ICD10 Code	Code Description	Recommended Placement
S06.36AA	Traumatic hemorrhage of cerebrum, unspecified, with loss of consciousness status unknown, initial encounter	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
S06.36AD	Traumatic hemorrhage of cerebrum, unspecified, with loss of consciousness status unknown, subsequent encounter	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
S06.36AS	Traumatic hemorrhage of cerebrum, unspecified, with loss of consciousness status unknown, sequela	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
S06.37AA	Contusion, laceration, and hemorrhage of cerebellum with loss of consciousness status unknown, initial encounter	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
S06.37AD	Contusion, laceration, and hemorrhage of cerebellum with loss of consciousness status unknown, subsequent encounter	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
S06.37AS	Contusion, laceration, and hemorrhage of cerebellum with loss of consciousness status unknown, sequela	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
S06.38AA	Contusion, laceration, and hemorrhage of brainstem with loss of consciousness status unknown, initial encounter	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
S06.38AD	Contusion, laceration, and hemorrhage of brainstem with loss of consciousness status unknown, subsequent encounter	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
S06.38AS	Contusion, laceration, and hemorrhage of brainstem with loss of consciousness status unknown, sequela	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN

Appendix B
New Codes

ICD10 Code	Code Description	Recommended Placement
S06.4XAA	Epidural hemorrhage with loss of consciousness status unknown, initial encounter	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
S06.4XAD	Epidural hemorrhage with loss of consciousness status unknown, subsequent encounter	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
S06.4XAS	Epidural hemorrhage with loss of consciousness status unknown, sequela	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
S06.5XAA	Traumatic subdural hemorrhage with loss of consciousness status unknown, initial encounter	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
S06.5XAD	Traumatic subdural hemorrhage with loss of consciousness status unknown, subsequent encounter	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
S06.5XAS	Traumatic subdural hemorrhage with loss of consciousness status unknown, sequela	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
S06.6XAA	Traumatic subarachnoid hemorrhage with loss of consciousness status unknown, initial encounter	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
S06.6XAD	Traumatic subarachnoid hemorrhage with loss of consciousness status unknown, subsequent encounter	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
S06.6XAS	Traumatic subarachnoid hemorrhage with loss of consciousness status unknown, sequela	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN

Appendix B
New Codes

ICD10 Code	Code Description	Recommended Placement
S06.81AA	Injury of right internal carotid artery, intracranial portion, not elsewhere classified with loss of consciousness status unknown, initial encounter	71,292,345,377
S06.81AD	Injury of right internal carotid artery, intracranial portion, not elsewhere classified with loss of consciousness status unknown, subsequent encounter	71,292,345,377
S06.81AS	Injury of right internal carotid artery, intracranial portion, not elsewhere classified with loss of consciousness status unknown, sequela	71,292,345,377
S06.82AA	Injury of left internal carotid artery, intracranial portion, not elsewhere classified with loss of consciousness status unknown, initial encounter	71,292,345,377
S06.82AD	Injury of left internal carotid artery, intracranial portion, not elsewhere classified with loss of consciousness status unknown, subsequent encounter	71,292,345,377
S06.82AS	Injury of left internal carotid artery, intracranial portion, not elsewhere classified with loss of consciousness status unknown, sequela	71,292,345,377
S06.89AA	Other specified intracranial injury with loss of consciousness status unknown, initial encounter	71,292,345,377
S06.89AD	Other specified intracranial injury with loss of consciousness status unknown, subsequent encounter	71,292,345,377
S06.89AS	Other specified intracranial injury with loss of consciousness status unknown, sequela	71,292,345,377
S06.8A0A	Primary blast injury of brain, not elsewhere classified without loss of consciousness, initial encounter	71,292,345,377
S06.8A0D	Primary blast injury of brain, not elsewhere classified without loss of consciousness, subsequent encounter	71,292,345,377
S06.8A0S	Primary blast injury of brain, not elsewhere classified without loss of consciousness, sequela	71,292,345,377
S06.8A1A	Primary blast injury of brain, not elsewhere classified with loss of consciousness of 30 minutes or less, initial encounter	71,292,345,377

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New Codes

ICD10 Code	Code Description	Recommended Placement
S06.8A1D	Primary blast injury of brain, not elsewhere classified with loss of consciousness of 30 minutes or less, subsequent encounter	71,292,345,377
S06.8A1S	Primary blast injury of brain, not elsewhere classified with loss of consciousness of 30 minutes or less, sequela	71,292,345,377
S06.8A2A	Primary blast injury of brain, not elsewhere classified with loss of consciousness of 31 minutes to 59 minutes, initial encounter	71,292,345,377
S06.8A2D	Primary blast injury of brain, not elsewhere classified with loss of consciousness of 31 minutes to 59 minutes, subsequent encounter	71,292,345,377
S06.8A2S	Primary blast injury of brain, not elsewhere classified with loss of consciousness of 31 minutes to 59 minutes, sequela	71,292,345,377
S06.8A3A	Primary blast injury of brain, not elsewhere classified with loss of consciousness of 1 hour to 5 hours 59 minutes, initial encounter	71,292,345,377
S06.8A3D	Primary blast injury of brain, not elsewhere classified with loss of consciousness of 1 hour to 5 hours 59 minutes, subsequent encounter	71,292,345,377
S06.8A3S	Primary blast injury of brain, not elsewhere classified with loss of consciousness of 1 hour to 5 hours 59 minutes, sequela	71,292,345,377
S06.8A4A	Primary blast injury of brain, not elsewhere classified with loss of consciousness of 6 hours to 24 hours, initial encounter	71,292,345,377
S06.8A4D	Primary blast injury of brain, not elsewhere classified with loss of consciousness of 6 hours to 24 hours, subsequent encounter	71,292,345,377
S06.8A4S	Primary blast injury of brain, not elsewhere classified with loss of consciousness of 6 hours to 24 hours, sequela	71,292,345,377

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New Codes

ICD10 Code	Code Description	Recommended Placement
S06.8A5A	Primary blast injury of brain, not elsewhere classified with loss of consciousness greater than 24 hours with return to pre-existing conscious level, initial encounter	71,292,345,377
S06.8A5D	Primary blast injury of brain, not elsewhere classified with loss of consciousness greater than 24 hours with return to pre-existing conscious level, subsequent encounter	71,292,345,377
S06.8A5S	Primary blast injury of brain, not elsewhere classified with loss of consciousness greater than 24 hours with return to pre-existing conscious level, sequela	71,292,345,377
S06.8A6A	Primary blast injury of brain, not elsewhere classified with loss of consciousness greater than 24 hours without return to pre-existing conscious level with patient surviving, initial encounter	71,292,345,377
S06.8A6D	Primary blast injury of brain, not elsewhere classified with loss of consciousness greater than 24 hours without return to pre-existing conscious level with patient surviving, subsequent encounter	71,292,345,377
S06.8A6S	Primary blast injury of brain, not elsewhere classified with loss of consciousness greater than 24 hours without return to pre-existing conscious level with patient surviving, sequela	71,292,345,377
S06.8A7A	Primary blast injury of brain, not elsewhere classified with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness, initial encounter	71,292,345,377
S06.8A8A	Primary blast injury of brain, not elsewhere classified with loss of consciousness of any duration with death due to other cause prior to regaining consciousness, initial encounter	71,292,345,377
S06.8A9A	Primary blast injury of brain, not elsewhere classified with loss of consciousness of unspecified duration, initial encounter	71,292,345,377

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New Codes

ICD10 Code	Code Description	Recommended Placement
S06.8A9D	Primary blast injury of brain, not elsewhere classified with loss of consciousness of unspecified duration, subsequent encounter	71,292,345,377
S06.8A9S	Primary blast injury of brain, not elsewhere classified with loss of consciousness of unspecified duration, sequela	71,292,345,377
S06.8AAA	Primary blast injury of brain, not elsewhere classified with loss of consciousness status unknown, initial encounter	71,292,345,377
S06.8AAD	Primary blast injury of brain, not elsewhere classified with loss of consciousness status unknown, subsequent encounter	71,292,345,377
S06.8AAS	Primary blast injury of brain, not elsewhere classified with loss of consciousness status unknown, sequela	71,292,345,377
S06.9XAA	Unspecified intracranial injury with loss of consciousness status unknown, initial encounter	71,292,345,377
S06.9XAD	Unspecified intracranial injury with loss of consciousness status unknown, subsequent encounter	71,292,345,377
S06.9XAS	Unspecified intracranial injury with loss of consciousness status unknown, sequela	71,292,345,377
T43.651A	Poisoning by methamphetamines accidental (unintentional), initial encounter	102 POISONING BY INGESTION, INJECTION, MEDICINAL AND NON-MEDICINAL AGENTS
T43.651D	Poisoning by methamphetamines accidental (unintentional), subsequent encounter	102 POISONING BY INGESTION, INJECTION, MEDICINAL AND NON-MEDICINAL AGENTS
T43.651S	Poisoning by methamphetamines accidental (unintentional), sequela	102 POISONING BY INGESTION, INJECTION, MEDICINAL AND NON-MEDICINAL AGENTS
T43.652A	Poisoning by methamphetamines intentional self-harm, initial encounter	102 POISONING BY INGESTION, INJECTION, MEDICINAL AND NON-MEDICINAL AGENTS
T43.652D	Poisoning by methamphetamines intentional self-harm, subsequent encounter	102 POISONING BY INGESTION, INJECTION, MEDICINAL AND NON-MEDICINAL AGENTS
T43.652S	Poisoning by methamphetamines intentional self-harm, sequela	102 POISONING BY INGESTION, INJECTION, MEDICINAL AND NON-MEDICINAL AGENTS

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New Codes

ICD10 Code	Code Description	Recommended Placement
T43.653A	Poisoning by methamphetamines, assault, initial encounter	102 POISONING BY INGESTION, INJECTION, MEDICINAL AND NON-MEDICINAL AGENTS
T43.653D	Poisoning by methamphetamines, assault, subsequent encounter	102 POISONING BY INGESTION, INJECTION, MEDICINAL AND NON-MEDICINAL AGENTS
T43.653S	Poisoning by methamphetamines, assault, sequela	102 POISONING BY INGESTION, INJECTION, MEDICINAL AND NON-MEDICINAL AGENTS
T43.654A	Poisoning by methamphetamines, undetermined, initial encounter	102 POISONING BY INGESTION, INJECTION, MEDICINAL AND NON-MEDICINAL AGENTS
T43.654D	Poisoning by methamphetamines, undetermined, subsequent encounter	102 POISONING BY INGESTION, INJECTION, MEDICINAL AND NON-MEDICINAL AGENTS
T43.654S	Poisoning by methamphetamines, undetermined, sequela	102 POISONING BY INGESTION, INJECTION, MEDICINAL AND NON-MEDICINAL AGENTS
T43.655A	Adverse effect of methamphetamines, initial encounter	102 POISONING BY INGESTION, INJECTION, MEDICINAL AND NON-MEDICINAL AGENTS
T43.655D	Adverse effect of methamphetamines, subsequent encounter	102 POISONING BY INGESTION, INJECTION, MEDICINAL AND NON-MEDICINAL AGENTS
T43.655S	Adverse effect of methamphetamines, sequela	102 POISONING BY INGESTION, INJECTION, MEDICINAL AND NON-MEDICINAL AGENTS
T43.656A	Underdosing of methamphetamines, initial encounter	DIAGNOSTIC WORKUP FILE (DWF)
T43.656D	Underdosing of methamphetamines, subsequent encounter	DIAGNOSTIC WORKUP FILE (DWF)
T43.656S	Underdosing of methamphetamines, sequela	DIAGNOSTIC WORKUP FILE (DWF)
V20.01XA	Electric (assisted) bicycle driver injured in collision with pedestrian or animal in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V20.01XD	Electric (assisted) bicycle driver injured in collision with pedestrian or animal in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V20.01XS	Electric (assisted) bicycle driver injured in collision with pedestrian or animal in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V20.09XA	Other motorcycle driver injured in collision with pedestrian or animal in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES

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New Codes

ICD10 Code	Code Description	Recommended Placement
V20.09XD	Other motorcycle driver injured in collision with pedestrian or animal in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V20.09XS	Other motorcycle driver injured in collision with pedestrian or animal in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V20.11XA	Electric (assisted) bicycle passenger injured in collision with pedestrian or animal in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V20.11XD	Electric (assisted) bicycle passenger injured in collision with pedestrian or animal in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V20.11XS	Electric (assisted) bicycle passenger injured in collision with pedestrian or animal in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V20.19XA	Other motorcycle passenger injured in collision with pedestrian or animal in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V20.19XD	Other motorcycle passenger injured in collision with pedestrian or animal in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V20.19XS	Other motorcycle passenger injured in collision with pedestrian or animal in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V20.21XA	Unspecified electric (assisted) bicycle rider injured in collision with pedestrian or animal in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V20.21XD	Unspecified electric (assisted) bicycle rider injured in collision with pedestrian or animal in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V20.21XS	Unspecified electric (assisted) bicycle rider injured in collision with pedestrian or animal in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V20.29XA	Unspecified rider of other motorcycle injured in collision with pedestrian or animal in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES

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New Codes

ICD10 Code	Code Description	Recommended Placement
V20.29XD	Unspecified rider of other motorcycle injured in collision with pedestrian or animal in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V20.29XS	Unspecified rider of other motorcycle injured in collision with pedestrian or animal in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V20.31XA	Person boarding or alighting an electric (assisted) bicycle injured in collision with pedestrian or animal, initial encounter	INFORMATIONAL DIAGNOSES
V20.31XD	Person boarding or alighting an electric (assisted) bicycle injured in collision with pedestrian or animal, subsequent encounter	INFORMATIONAL DIAGNOSES
V20.31XS	Person boarding or alighting an electric (assisted) bicycle injured in collision with pedestrian or animal, sequela	INFORMATIONAL DIAGNOSES
V20.39XA	Person boarding or alighting other motorcycle injured in collision with pedestrian or animal, initial encounter	INFORMATIONAL DIAGNOSES
V20.39XD	Person boarding or alighting other motorcycle injured in collision with pedestrian or animal, subsequent encounter	INFORMATIONAL DIAGNOSES
V20.39XS	Person boarding or alighting other motorcycle injured in collision with pedestrian or animal, sequela	INFORMATIONAL DIAGNOSES
V20.41XA	Electric (assisted) bicycle driver injured in collision with pedestrian or animal in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V20.41XD	Electric (assisted) bicycle driver injured in collision with pedestrian or animal in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V20.41XS	Electric (assisted) bicycle driver injured in collision with pedestrian or animal in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V20.49XA	Other motorcycle driver injured in collision with pedestrian or animal in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V20.49XD	Other motorcycle driver injured in collision with pedestrian or animal in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V20.49XS	Other motorcycle driver injured in collision with pedestrian or animal in traffic accident, sequela	INFORMATIONAL DIAGNOSES

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New Codes

ICD10 Code	Code Description	Recommended Placement
V20.51XA	Electric (assisted) bicycle passenger injured in collision with pedestrian or animal in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V20.51XD	Electric (assisted) bicycle passenger injured in collision with pedestrian or animal in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V20.51XS	Electric (assisted) bicycle passenger injured in collision with pedestrian or animal in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V20.59XA	Other motorcycle passenger injured in collision with pedestrian or animal in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V20.59XD	Other motorcycle passenger injured in collision with pedestrian or animal in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V20.59XS	Other motorcycle passenger injured in collision with pedestrian or animal in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V20.91XA	Unspecified electric (assisted) bicycle rider injured in collision with pedestrian or animal in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V20.91XD	Unspecified electric (assisted) bicycle rider injured in collision with pedestrian or animal in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V20.91XS	Unspecified electric (assisted) bicycle rider injured in collision with pedestrian or animal in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V20.99XA	Unspecified rider of other motorcycle injured in collision with pedestrian or animal in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V20.99XD	Unspecified rider of other motorcycle injured in collision with pedestrian or animal in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V20.99XS	Unspecified rider of other motorcycle injured in collision with pedestrian or animal in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V21.01XA	Electric (assisted) bicycle driver injured in collision with pedal cycle in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V21.01XD	Electric (assisted) bicycle driver injured in collision with pedal cycle in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES

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New Codes

ICD10 Code	Code Description	Recommended Placement
V21.01XS	Electric (assisted) bicycle driver injured in collision with pedal cycle in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V21.09XA	Other motorcycle driver injured in collision with pedal cycle in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V21.09XD	Other motorcycle driver injured in collision with pedal cycle in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V21.09XS	Other motorcycle driver injured in collision with pedal cycle in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V21.11XA	Electric (assisted) bicycle passenger injured in collision with pedal cycle in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V21.11XD	Electric (assisted) bicycle passenger injured in collision with pedal cycle in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V21.11XS	Electric (assisted) bicycle passenger injured in collision with pedal cycle in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V21.19XA	Other motorcycle passenger injured in collision with pedal cycle in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V21.19XD	Other motorcycle passenger injured in collision with pedal cycle in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V21.19XS	Other motorcycle passenger injured in collision with pedal cycle in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V21.21XA	Unspecified electric (assisted) bicycle rider injured in collision with pedal cycle in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V21.21XD	Unspecified electric (assisted) bicycle rider injured in collision with pedal cycle in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V21.21XS	Unspecified electric (assisted) bicycle rider injured in collision with pedal cycle in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V21.29XA	Unspecified rider of other motorcycle injured in collision with pedal cycle in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES

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New Codes

ICD10 Code	Code Description	Recommended Placement
V21.29XD	Unspecified rider of other motorcycle injured in collision with pedal cycle in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V21.29XS	Unspecified rider of other motorcycle injured in collision with pedal cycle in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V21.31XA	Person boarding or alighting an electric (assisted) bicycle injured in collision with pedal cycle, initial encounter	INFORMATIONAL DIAGNOSES
V21.31XD	Person boarding or alighting an electric (assisted) bicycle injured in collision with pedal cycle, subsequent encounter	INFORMATIONAL DIAGNOSES
V21.31XS	Person boarding or alighting an electric (assisted) bicycle injured in collision with pedal cycle, sequela	INFORMATIONAL DIAGNOSES
V21.39XA	Person boarding or alighting other motorcycle injured in collision with pedal cycle, initial encounter	INFORMATIONAL DIAGNOSES
V21.39XD	Person boarding or alighting other motorcycle injured in collision with pedal cycle, subsequent encounter	INFORMATIONAL DIAGNOSES
V21.39XS	Person boarding or alighting other motorcycle injured in collision with pedal cycle, sequela	INFORMATIONAL DIAGNOSES
V21.41XA	Electric (assisted) bicycle driver injured in collision with pedal cycle in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V21.41XD	Electric (assisted) bicycle driver injured in collision with pedal cycle in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V21.41XS	Electric (assisted) bicycle driver injured in collision with pedal cycle in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V21.49XA	Other motorcycle driver injured in collision with pedal cycle in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V21.49XD	Other motorcycle driver injured in collision with pedal cycle in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V21.49XS	Other motorcycle driver injured in collision with pedal cycle in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V21.51XA	Electric (assisted) bicycle passenger injured in collision with pedal cycle in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES

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New Codes

ICD10 Code	Code Description	Recommended Placement
V21.51XD	Electric (assisted) bicycle passenger injured in collision with pedal cycle in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V21.51XS	Electric (assisted) bicycle passenger injured in collision with pedal cycle in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V21.59XA	Other motorcycle passenger injured in collision with pedal cycle in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V21.59XD	Other motorcycle passenger injured in collision with pedal cycle in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V21.59XS	Other motorcycle passenger injured in collision with pedal cycle in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V21.91XA	Unspecified electric (assisted) bicycle rider injured in collision with pedal cycle in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V21.91XD	Unspecified electric (assisted) bicycle rider injured in collision with pedal cycle in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V21.91XS	Unspecified electric (assisted) bicycle rider injured in collision with pedal cycle in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V21.99XA	Unspecified rider of other motorcycle injured in collision with pedal cycle in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V21.99XD	Unspecified rider of other motorcycle injured in collision with pedal cycle in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V21.99XS	Unspecified rider of other motorcycle injured in collision with pedal cycle in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V22.01XA	Electric (assisted) bicycle driver injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V22.01XD	Electric (assisted) bicycle driver injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V22.01XS	Electric (assisted) bicycle driver injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES

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New Codes

ICD10 Code	Code Description	Recommended Placement
V22.09XA	Other motorcycle driver injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V22.09XD	Other motorcycle driver injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V22.09XS	Other motorcycle driver injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V22.11XA	Electric (assisted) bicycle passenger injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V22.11XD	Electric (assisted) bicycle passenger injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V22.11XS	Electric (assisted) bicycle passenger injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V22.19XA	Other motorcycle passenger injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V22.19XD	Other motorcycle passenger injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V22.19XS	Other motorcycle passenger injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V22.21XA	Unspecified electric (assisted) bicycle rider injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V22.21XD	Unspecified electric (assisted) bicycle rider injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V22.21XS	Unspecified electric (assisted) bicycle rider injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V22.29XA	Unspecified rider of other motorcycle injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V22.29XD	Unspecified rider of other motorcycle injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V22.29XS	Unspecified rider of other motorcycle injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V22.31XA	Person boarding or alighting an electric (assisted) bicycle injured in collision with two- or three-wheeled motor vehicle, initial encounter	INFORMATIONAL DIAGNOSES
V22.31XD	Person boarding or alighting an electric (assisted) bicycle injured in collision with two- or three-wheeled motor vehicle, subsequent encounter	INFORMATIONAL DIAGNOSES
V22.31XS	Person boarding or alighting an electric (assisted) bicycle injured in collision with two- or three-wheeled motor vehicle, sequela	INFORMATIONAL DIAGNOSES
V22.39XA	Person boarding or alighting other motorcycle injured in collision with two- or three-wheeled motor vehicle, initial encounter	INFORMATIONAL DIAGNOSES
V22.39XD	Person boarding or alighting other motorcycle injured in collision with two- or three-wheeled motor vehicle, subsequent encounter	INFORMATIONAL DIAGNOSES
V22.39XS	Person boarding or alighting other motorcycle injured in collision with two- or three-wheeled motor vehicle, sequela	INFORMATIONAL DIAGNOSES
V22.41XA	Electric (assisted) bicycle driver injured in collision with two- or three-wheeled motor vehicle in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V22.41XD	Electric (assisted) bicycle driver injured in collision with two- or three-wheeled motor vehicle in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V22.41XS	Electric (assisted) bicycle driver injured in collision with two- or three-wheeled motor vehicle in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V22.49XA	Other motorcycle driver injured in collision with two- or three-wheeled motor vehicle in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V22.49XD	Other motorcycle driver injured in collision with two- or three-wheeled motor vehicle in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V22.49XS	Other motorcycle driver injured in collision with two- or three-wheeled motor vehicle in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V22.51XA	Electric (assisted) bicycle passenger injured in collision with two- or three-wheeled motor vehicle in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V22.51XD	Electric (assisted) bicycle passenger injured in collision with two- or three-wheeled motor vehicle in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V22.51XS	Electric (assisted) bicycle passenger injured in collision with two- or three-wheeled motor vehicle in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V22.59XA	Other motorcycle passenger injured in collision with two- or three-wheeled motor vehicle in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V22.59XD	Other motorcycle passenger injured in collision with two- or three-wheeled motor vehicle in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V22.59XS	Other motorcycle passenger injured in collision with two- or three-wheeled motor vehicle in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V22.91XA	Unspecified electric (assisted) bicycle rider injured in collision with two- or three-wheeled motor vehicle in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES

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New Codes

ICD10 Code	Code Description	Recommended Placement
V22.91XD	Unspecified electric (assisted) bicycle rider injured in collision with two- or three-wheeled motor vehicle in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V22.91XS	Unspecified electric (assisted) bicycle rider injured in collision with two- or three-wheeled motor vehicle in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V22.99XA	Unspecified rider of other motorcycle injured in collision with two- or three-wheeled motor vehicle in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V22.99XD	Unspecified rider of other motorcycle injured in collision with two- or three-wheeled motor vehicle in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V22.99XS	Unspecified rider of other motorcycle injured in collision with two- or three-wheeled motor vehicle in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V23.01XA	Electric (assisted) bicycle driver injured in collision with car, pick-up truck or van in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V23.01XD	Electric (assisted) bicycle driver injured in collision with car, pick-up truck or van in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V23.01XS	Electric (assisted) bicycle driver injured in collision with car, pick-up truck or van in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V23.09XA	Other motorcycle driver injured in collision with car, pick-up truck or van in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V23.09XD	Other motorcycle driver injured in collision with car, pick-up truck or van in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V23.09XS	Other motorcycle driver injured in collision with car, pick-up truck or van in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V23.11XA	Electric (assisted) bicycle passenger injured in collision with car, pick-up truck or van in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES

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New Codes

ICD10 Code	Code Description	Recommended Placement
V23.11XD	Electric (assisted) bicycle passenger injured in collision with car, pick-up truck or van in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V23.11XS	Electric (assisted) bicycle passenger injured in collision with car, pick-up truck or van in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V23.19XA	Other motorcycle passenger injured in collision with car, pick-up truck or van in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V23.19XD	Other motorcycle passenger injured in collision with car, pick-up truck or van in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V23.19XS	Other motorcycle passenger injured in collision with car, pick-up truck or van in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V23.21XA	Unspecified electric (assisted) bicycle rider injured in collision with car, pick-up truck or van in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V23.21XD	Unspecified electric (assisted) bicycle rider injured in collision with car, pick-up truck or van in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V23.21XS	Unspecified electric (assisted) bicycle rider injured in collision with car, pick-up truck or van in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V23.29XA	Unspecified rider of other motorcycle injured in collision with car, pick-up truck or van in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V23.29XD	Unspecified rider of other motorcycle injured in collision with car, pick-up truck or van in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V23.29XS	Unspecified rider of other motorcycle injured in collision with car, pick-up truck or van in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V23.31XA	Person boarding or alighting an electric (assisted) bicycle injured in collision with car, pick-up truck or van, initial encounter	INFORMATIONAL DIAGNOSES
V23.31XD	Person boarding or alighting an electric (assisted) bicycle injured in collision with car, pick-up truck or van, subsequent encounter	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V23.31XS	Person boarding or alighting an electric (assisted) bicycle injured in collision with car, pick-up truck or van, sequela	INFORMATIONAL DIAGNOSES
V23.39XA	Person boarding or alighting other motorcycle injured in collision with car, pick-up truck or van, initial encounter	INFORMATIONAL DIAGNOSES
V23.39XD	Person boarding or alighting other motorcycle injured in collision with car, pick-up truck or van, subsequent encounter	INFORMATIONAL DIAGNOSES
V23.39XS	Person boarding or alighting other motorcycle injured in collision with car, pick-up truck or van, sequela	INFORMATIONAL DIAGNOSES
V23.41XA	Electric (assisted) bicycle driver injured in collision with car, pick-up truck or van in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V23.41XD	Electric (assisted) bicycle driver injured in collision with car, pick-up truck or van in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V23.41XS	Electric (assisted) bicycle driver injured in collision with car, pick-up truck or van in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V23.49XA	Other motorcycle driver injured in collision with car, pick-up truck or van in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V23.49XD	Other motorcycle driver injured in collision with car, pick-up truck or van in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V23.49XS	Other motorcycle driver injured in collision with car, pick-up truck or van in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V23.51XA	Electric (assisted) bicycle passenger injured in collision with car, pick-up truck or van in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V23.51XD	Electric (assisted) bicycle passenger injured in collision with car, pick-up truck or van in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V23.51XS	Electric (assisted) bicycle passenger injured in collision with car, pick-up truck or van in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V23.59XA	Other motorcycle passenger injured in collision with car, pick-up truck or van in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES

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New Codes

ICD10 Code	Code Description	Recommended Placement
V23.59XD	Other motorcycle passenger injured in collision with car, pick-up truck or van in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V23.59XS	Other motorcycle passenger injured in collision with car, pick-up truck or van in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V23.91XA	Unspecified electric (assisted) bicycle rider injured in collision with car, pick-up truck or van in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V23.91XD	Unspecified electric (assisted) bicycle rider injured in collision with car, pick-up truck or van in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V23.91XS	Unspecified electric (assisted) bicycle rider injured in collision with car, pick-up truck or van in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V23.99XA	Unspecified rider of other motorcycle injured in collision with car, pick-up truck or van in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V23.99XD	Unspecified rider of other motorcycle injured in collision with car, pick-up truck or van in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V23.99XS	Unspecified rider of other motorcycle injured in collision with car, pick-up truck or van in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V24.01XA	Electric (assisted) bicycle driver injured in collision with heavy transport vehicle or bus in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V24.01XD	Electric (assisted) bicycle driver injured in collision with heavy transport vehicle or bus in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V24.01XS	Electric (assisted) bicycle driver injured in collision with heavy transport vehicle or bus in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V24.09XA	Other motorcycle driver injured in collision with heavy transport vehicle or bus in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V24.09XD	Other motorcycle driver injured in collision with heavy transport vehicle or bus in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V24.09XS	Other motorcycle driver injured in collision with heavy transport vehicle or bus in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V24.11XA	Electric (assisted) bicycle passenger injured in collision with heavy transport vehicle or bus in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V24.11XD	Electric (assisted) bicycle passenger injured in collision with heavy transport vehicle or bus in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V24.11XS	Electric (assisted) bicycle passenger injured in collision with heavy transport vehicle or bus in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V24.19XA	Other motorcycle passenger injured in collision with heavy transport vehicle or bus in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V24.19XD	Other motorcycle passenger injured in collision with heavy transport vehicle or bus in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V24.19XS	Other motorcycle passenger injured in collision with heavy transport vehicle or bus in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V24.21XA	Unspecified electric (assisted) bicycle rider injured in collision with heavy transport vehicle or bus in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V24.21XD	Unspecified electric (assisted) bicycle rider injured in collision with heavy transport vehicle or bus in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V24.21XS	Unspecified electric (assisted) bicycle rider injured in collision with heavy transport vehicle or bus in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V24.29XA	Unspecified rider of other motorcycle injured in collision with heavy transport vehicle or bus in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V24.29XD	Unspecified rider of other motorcycle injured in collision with heavy transport vehicle or bus in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V24.29XS	Unspecified rider of other motorcycle injured in collision with heavy transport vehicle or bus in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V24.31XA	Person boarding or alighting an electric (assisted) bicycle injured in collision with heavy transport vehicle or bus, initial encounter	INFORMATIONAL DIAGNOSES
V24.31XD	Person boarding or alighting an electric (assisted) bicycle injured in collision with heavy transport vehicle or bus, subsequent encounter	INFORMATIONAL DIAGNOSES
V24.31XS	Person boarding or alighting an electric (assisted) bicycle injured in collision with heavy transport vehicle or bus, sequela	INFORMATIONAL DIAGNOSES
V24.39XA	Person boarding or alighting other motorcycle injured in collision with heavy transport vehicle or bus, initial encounter	INFORMATIONAL DIAGNOSES
V24.39XD	Person boarding or alighting other motorcycle injured in collision with heavy transport vehicle or bus, subsequent encounter	INFORMATIONAL DIAGNOSES
V24.39XS	Person boarding or alighting other motorcycle injured in collision with heavy transport vehicle or bus, sequela	INFORMATIONAL DIAGNOSES
V24.41XA	Electric (assisted) bicycle driver injured in collision with heavy transport vehicle or bus in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V24.41XD	Electric (assisted) bicycle driver injured in collision with heavy transport vehicle or bus in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V24.41XS	Electric (assisted) bicycle driver injured in collision with heavy transport vehicle or bus in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V24.49XA	Other motorcycle driver injured in collision with heavy transport vehicle or bus in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V24.49XD	Other motorcycle driver injured in collision with heavy transport vehicle or bus in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V24.49XS	Other motorcycle driver injured in collision with heavy transport vehicle or bus in traffic accident, sequela	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V24.51XA	Electric (assisted) bicycle passenger injured in collision with heavy transport vehicle or bus in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V24.51XD	Electric (assisted) bicycle passenger injured in collision with heavy transport vehicle or bus in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V24.51XS	Electric (assisted) bicycle passenger injured in collision with heavy transport vehicle or bus in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V24.59XA	Other motorcycle passenger injured in collision with heavy transport vehicle or bus in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V24.59XD	Other motorcycle passenger injured in collision with heavy transport vehicle or bus in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V24.59XS	Other motorcycle passenger injured in collision with heavy transport vehicle or bus in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V24.91XA	Unspecified electric (assisted) bicycle rider injured in collision with heavy transport vehicle or bus in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V24.91XD	Unspecified electric (assisted) bicycle rider injured in collision with heavy transport vehicle or bus in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V24.91XS	Unspecified electric (assisted) bicycle rider injured in collision with heavy transport vehicle or bus in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V24.99XA	Unspecified rider of other motorcycle injured in collision with heavy transport vehicle or bus in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V24.99XD	Unspecified rider of other motorcycle injured in collision with heavy transport vehicle or bus in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V24.99XS	Unspecified rider of other motorcycle injured in collision with heavy transport vehicle or bus in traffic accident, sequela	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V25.01XA	Electric (assisted) bicycle driver injured in collision with railway train or railway vehicle in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V25.01XD	Electric (assisted) bicycle driver injured in collision with railway train or railway vehicle in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V25.01XS	Electric (assisted) bicycle driver injured in collision with railway train or railway vehicle in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V25.09XA	Other motorcycle driver injured in collision with railway train or railway vehicle in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V25.09XD	Other motorcycle driver injured in collision with railway train or railway vehicle in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V25.09XS	Other motorcycle driver injured in collision with railway train or railway vehicle in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V25.11XA	Electric (assisted) bicycle passenger injured in collision with railway train or railway vehicle in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V25.11XD	Electric (assisted) bicycle passenger injured in collision with railway train or railway vehicle in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V25.11XS	Electric (assisted) bicycle passenger injured in collision with railway train or railway vehicle in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V25.19XA	Other motorcycle passenger injured in collision with railway train or railway vehicle in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V25.19XD	Other motorcycle passenger injured in collision with railway train or railway vehicle in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V25.19XS	Other motorcycle passenger injured in collision with railway train or railway vehicle in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V25.21XA	Unspecified electric (assisted) bicycle rider injured in collision with railway train or railway vehicle in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V25.21XD	Unspecified electric (assisted) bicycle rider injured in collision with railway train or railway vehicle in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V25.21XS	Unspecified electric (assisted) bicycle rider injured in collision with railway train or railway vehicle in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V25.29XA	Unspecified rider of other motorcycle injured in collision with railway train or railway vehicle in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V25.29XD	Unspecified rider of other motorcycle injured in collision with railway train or railway vehicle in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V25.29XS	Unspecified rider of other motorcycle injured in collision with railway train or railway vehicle in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V25.31XA	Person boarding or alighting an electric (assisted) bicycle injured in collision with railway train or railway vehicle, initial encounter	INFORMATIONAL DIAGNOSES
V25.31XD	Person boarding or alighting an electric (assisted) bicycle injured in collision with railway train or railway vehicle, subsequent encounter	INFORMATIONAL DIAGNOSES
V25.31XS	Person boarding or alighting an electric (assisted) bicycle injured in collision with railway train or railway vehicle, sequela	INFORMATIONAL DIAGNOSES
V25.39XA	Person boarding or alighting other motorcycle injured in collision with railway train or railway vehicle, initial encounter	INFORMATIONAL DIAGNOSES
V25.39XD	Person boarding or alighting other motorcycle injured in collision with railway train or railway vehicle, subsequent encounter	INFORMATIONAL DIAGNOSES
V25.39XS	Person boarding or alighting other motorcycle injured in collision with railway train or railway vehicle, sequela	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V25.41XA	Electric (assisted) bicycle driver injured in collision with railway train or railway vehicle in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V25.41XD	Electric (assisted) bicycle driver injured in collision with railway train or railway vehicle in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V25.41XS	Electric (assisted) bicycle driver injured in collision with railway train or railway vehicle in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V25.49XA	Other motorcycle driver injured in collision with railway train or railway vehicle in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V25.49XD	Other motorcycle driver injured in collision with railway train or railway vehicle in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V25.49XS	Other motorcycle driver injured in collision with railway train or railway vehicle in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V25.51XA	Electric (assisted) bicycle passenger injured in collision with railway train or railway vehicle in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V25.51XD	Electric (assisted) bicycle passenger injured in collision with railway train or railway vehicle in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V25.51XS	Electric (assisted) bicycle passenger injured in collision with railway train or railway vehicle in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V25.59XA	Other motorcycle passenger injured in collision with railway train or railway vehicle in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V25.59XD	Other motorcycle passenger injured in collision with railway train or railway vehicle in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V25.59XS	Other motorcycle passenger injured in collision with railway train or railway vehicle in traffic accident, sequela	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V25.91XA	Unspecified electric (assisted) bicycle rider injured in collision with railway train or railway vehicle in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V25.91XD	Unspecified electric (assisted) bicycle rider injured in collision with railway train or railway vehicle in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V25.91XS	Unspecified electric (assisted) bicycle rider injured in collision with railway train or railway vehicle in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V25.99XA	Unspecified rider of other motorcycle injured in collision with railway train or railway vehicle in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V25.99XD	Unspecified rider of other motorcycle injured in collision with railway train or railway vehicle in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V25.99XS	Unspecified rider of other motorcycle injured in collision with railway train or railway vehicle in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V26.01XA	Electric (assisted) bicycle driver injured in collision with other nonmotor vehicle in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V26.01XD	Electric (assisted) bicycle driver injured in collision with other nonmotor vehicle in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V26.01XS	Electric (assisted) bicycle driver injured in collision with other nonmotor vehicle in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V26.09XA	Other motorcycle driver injured in collision with other nonmotor vehicle in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V26.09XD	Other motorcycle driver injured in collision with other nonmotor vehicle in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V26.09XS	Other motorcycle driver injured in collision with other nonmotor vehicle in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V26.11XA	Electric (assisted) bicycle passenger injured in collision with other nonmotor vehicle in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V26.11XD	Electric (assisted) bicycle passenger injured in collision with other nonmotor vehicle in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V26.11XS	Electric (assisted) bicycle passenger injured in collision with other nonmotor vehicle in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V26.19XA	Other motorcycle passenger injured in collision with other nonmotor vehicle in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V26.19XD	Other motorcycle passenger injured in collision with other nonmotor vehicle in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V26.19XS	Other motorcycle passenger injured in collision with other nonmotor vehicle in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V26.21XA	Unspecified electric (assisted) bicycle rider injured in collision with other nonmotor vehicle in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V26.21XD	Unspecified electric (assisted) bicycle rider injured in collision with other nonmotor vehicle in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V26.21XS	Unspecified electric (assisted) bicycle rider injured in collision with other nonmotor vehicle in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V26.29XA	Unspecified rider of other motorcycle injured in collision with other nonmotor vehicle in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V26.29XD	Unspecified rider of other motorcycle injured in collision with other nonmotor vehicle in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V26.29XS	Unspecified rider of other motorcycle injured in collision with other nonmotor vehicle in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V26.31XA	Person boarding or alighting an electric (assisted) bicycle injured in collision with other nonmotor vehicle, initial encounter	INFORMATIONAL DIAGNOSES
V26.31XD	Person boarding or alighting an electric (assisted) bicycle injured in collision with other nonmotor vehicle, subsequent encounter	INFORMATIONAL DIAGNOSES
V26.31XS	Person boarding or alighting an electric (assisted) bicycle injured in collision with other nonmotor vehicle, sequela	INFORMATIONAL DIAGNOSES
V26.39XA	Person boarding or alighting other motorcycle injured in collision with other nonmotor vehicle, initial encounter	INFORMATIONAL DIAGNOSES
V26.39XD	Person boarding or alighting other motorcycle injured in collision with other nonmotor vehicle, subsequent encounter	INFORMATIONAL DIAGNOSES
V26.39XS	Person boarding or alighting other motorcycle injured in collision with other nonmotor vehicle, sequela	INFORMATIONAL DIAGNOSES
V26.41XA	Electric (assisted) bicycle driver injured in collision with other nonmotor vehicle in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V26.41XD	Electric (assisted) bicycle driver injured in collision with other nonmotor vehicle in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V26.41XS	Electric (assisted) bicycle driver injured in collision with other nonmotor vehicle in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V26.49XA	Other motorcycle driver injured in collision with other nonmotor vehicle in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V26.49XD	Other motorcycle driver injured in collision with other nonmotor vehicle in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V26.49XS	Other motorcycle driver injured in collision with other nonmotor vehicle in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V26.51XA	Electric (assisted) bicycle passenger injured in collision with other nonmotor vehicle in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V26.51XD	Electric (assisted) bicycle passenger injured in collision with other nonmotor vehicle in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES

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New Codes

ICD10 Code	Code Description	Recommended Placement
V26.51XS	Electric (assisted) bicycle passenger injured in collision with other nonmotor vehicle in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V26.59XA	Other motorcycle passenger injured in collision with other nonmotor vehicle in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V26.59XD	Other motorcycle passenger injured in collision with other nonmotor vehicle in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V26.59XS	Other motorcycle passenger injured in collision with other nonmotor vehicle in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V26.91XA	Unspecified electric (assisted) bicycle rider injured in collision with other nonmotor vehicle in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V26.91XD	Unspecified electric (assisted) bicycle rider injured in collision with other nonmotor vehicle in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V26.91XS	Unspecified electric (assisted) bicycle rider injured in collision with other nonmotor vehicle in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V26.99XA	Unspecified rider of other motorcycle injured in collision with other nonmotor vehicle in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V26.99XD	Unspecified rider of other motorcycle injured in collision with other nonmotor vehicle in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V26.99XS	Unspecified rider of other motorcycle injured in collision with other nonmotor vehicle in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V27.01XA	Electric (assisted) bicycle driver injured in collision with fixed or stationary object in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V27.01XD	Electric (assisted) bicycle driver injured in collision with fixed or stationary object in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V27.01XS	Electric (assisted) bicycle driver injured in collision with fixed or stationary object in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V27.09XA	Other motorcycle driver injured in collision with fixed or stationary object in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V27.09XD	Other motorcycle driver injured in collision with fixed or stationary object in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V27.09XS	Other motorcycle driver injured in collision with fixed or stationary object in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V27.11XA	Electric (assisted) bicycle passenger injured in collision with fixed or stationary object in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V27.11XD	Electric (assisted) bicycle passenger injured in collision with fixed or stationary object in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V27.11XS	Electric (assisted) bicycle passenger injured in collision with fixed or stationary object in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V27.19XA	Other motorcycle passenger injured in collision with fixed or stationary object in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V27.19XD	Other motorcycle passenger injured in collision with fixed or stationary object in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V27.19XS	Other motorcycle passenger injured in collision with fixed or stationary object in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V27.21XA	Unspecified electric (assisted) bicycle rider injured in collision with fixed or stationary object in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V27.21XD	Unspecified electric (assisted) bicycle rider injured in collision with fixed or stationary object in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V27.21XS	Unspecified electric (assisted) bicycle rider injured in collision with fixed or stationary object in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V27.29XA	Unspecified rider of other motorcycle injured in collision with fixed or stationary object in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V27.29XD	Unspecified rider of other motorcycle injured in collision with fixed or stationary object in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V27.29XS	Unspecified rider of other motorcycle injured in collision with fixed or stationary object in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V27.31XA	Person boarding or alighting an electric (assisted) bicycle injured in collision with fixed or stationary object, initial encounter	INFORMATIONAL DIAGNOSES
V27.31XD	Person boarding or alighting an electric (assisted) bicycle injured in collision with fixed or stationary object, subsequent encounter	INFORMATIONAL DIAGNOSES
V27.31XS	Person boarding or alighting an electric (assisted) bicycle injured in collision with fixed or stationary object, sequela	INFORMATIONAL DIAGNOSES
V27.39XA	Person boarding or alighting other motorcycle injured in collision with fixed or stationary object, initial encounter	INFORMATIONAL DIAGNOSES
V27.39XD	Person boarding or alighting other motorcycle injured in collision with fixed or stationary object, subsequent encounter	INFORMATIONAL DIAGNOSES
V27.39XS	Person boarding or alighting other motorcycle injured in collision with fixed or stationary object, sequela	INFORMATIONAL DIAGNOSES
V27.41XA	Electric (assisted) bicycle driver injured in collision with fixed or stationary object in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V27.41XD	Electric (assisted) bicycle driver injured in collision with fixed or stationary object in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V27.41XS	Electric (assisted) bicycle driver injured in collision with fixed or stationary object in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V27.49XA	Other motorcycle driver injured in collision with fixed or stationary object in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V27.49XD	Other motorcycle driver injured in collision with fixed or stationary object in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V27.49XS	Other motorcycle driver injured in collision with fixed or stationary object in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V27.51XA	Electric (assisted) bicycle passenger injured in collision with fixed or stationary object in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V27.51XD	Electric (assisted) bicycle passenger injured in collision with fixed or stationary object in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V27.51XS	Electric (assisted) bicycle passenger injured in collision with fixed or stationary object in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V27.59XA	Other motorcycle passenger injured in collision with fixed or stationary object in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V27.59XD	Other motorcycle passenger injured in collision with fixed or stationary object in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V27.59XS	Other motorcycle passenger injured in collision with fixed or stationary object in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V27.91XA	Unspecified electric (assisted) bicycle rider injured in collision with fixed or stationary object in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V27.91XD	Unspecified electric (assisted) bicycle rider injured in collision with fixed or stationary object in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V27.91XS	Unspecified electric (assisted) bicycle rider injured in collision with fixed or stationary object in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V27.99XA	Unspecified rider of other motorcycle injured in collision with fixed or stationary object in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V27.99XD	Unspecified rider of other motorcycle injured in collision with fixed or stationary object in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V27.99XS	Unspecified rider of other motorcycle injured in collision with fixed or stationary object in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V28.01XA	Electric (assisted) bicycle driver injured in noncollision transport accident in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V28.01XD	Electric (assisted) bicycle driver injured in noncollision transport accident in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V28.01XS	Electric (assisted) bicycle driver injured in noncollision transport accident in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V28.09XA	Other motorcycle driver injured in noncollision transport accident in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V28.09XD	Other motorcycle driver injured in noncollision transport accident in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V28.09XS	Other motorcycle driver injured in noncollision transport accident in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V28.11XA	Electric (assisted) bicycle passenger injured in noncollision transport accident in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V28.11XD	Electric (assisted) bicycle passenger injured in noncollision transport accident in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V28.11XS	Electric (assisted) bicycle passenger injured in noncollision transport accident in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V28.19XA	Other motorcycle passenger injured in noncollision transport accident in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V28.19XD	Other motorcycle passenger injured in noncollision transport accident in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V28.19XS	Other motorcycle passenger injured in noncollision transport accident in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V28.21XA	Unspecified electric (assisted) bicycle rider injured in noncollision transport accident in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V28.21XD	Unspecified electric (assisted) bicycle rider injured in noncollision transport accident in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V28.21XS	Unspecified electric (assisted) bicycle rider injured in noncollision transport accident in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V28.29XA	Unspecified rider of other motorcycle injured in noncollision transport accident in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V28.29XD	Unspecified rider of other motorcycle injured in noncollision transport accident in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V28.29XS	Unspecified rider of other motorcycle injured in noncollision transport accident in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V28.31XA	Person boarding or alighting an electric (assisted) bicycle injured in noncollision transport accident, initial encounter	INFORMATIONAL DIAGNOSES
V28.31XD	Person boarding or alighting an electric (assisted) bicycle injured in noncollision transport accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V28.31XS	Person boarding or alighting an electric (assisted) bicycle injured in noncollision transport accident, sequela	INFORMATIONAL DIAGNOSES
V28.39XA	Person boarding or alighting other motorcycle injured in noncollision transport accident, initial encounter	INFORMATIONAL DIAGNOSES
V28.39XD	Person boarding or alighting other motorcycle injured in noncollision transport accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V28.39XS	Person boarding or alighting other motorcycle injured in noncollision transport accident, sequela	INFORMATIONAL DIAGNOSES
V28.41XA	Electric (assisted) bicycle driver injured in noncollision transport accident in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V28.41XD	Electric (assisted) bicycle driver injured in noncollision transport accident in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V28.41XS	Electric (assisted) bicycle driver injured in noncollision transport accident in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V28.49XA	Other motorcycle driver injured in noncollision transport accident in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V28.49XD	Other motorcycle driver injured in noncollision transport accident in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V28.49XS	Other motorcycle driver injured in noncollision transport accident in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V28.51XA	Electric (assisted) bicycle passenger injured in noncollision transport accident in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V28.51XD	Electric (assisted) bicycle passenger injured in noncollision transport accident in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V28.51XS	Electric (assisted) bicycle passenger injured in noncollision transport accident in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V28.59XA	Other motorcycle passenger injured in noncollision transport accident in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V28.59XD	Other motorcycle passenger injured in noncollision transport accident in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V28.59XS	Other motorcycle passenger injured in noncollision transport accident in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V28.91XA	Unspecified electric (assisted) bicycle rider injured in noncollision transport accident in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V28.91XD	Unspecified electric (assisted) bicycle rider injured in noncollision transport accident in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V28.91XS	Unspecified electric (assisted) bicycle rider injured in noncollision transport accident in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V28.99XA	Unspecified rider of other motorcycle injured in noncollision transport accident in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V28.99XD	Unspecified rider of other motorcycle injured in noncollision transport accident in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V28.99XS	Unspecified rider of other motorcycle injured in noncollision transport accident in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V29.001A	Electric (assisted) bicycle driver injured in collision with unspecified motor vehicles in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.001D	Electric (assisted) bicycle driver injured in collision with unspecified motor vehicles in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.001S	Electric (assisted) bicycle driver injured in collision with unspecified motor vehicles in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V29.008A	Other motorcycle driver injured in collision with unspecified motor vehicles in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.008D	Other motorcycle driver injured in collision with unspecified motor vehicles in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.008S	Other motorcycle driver injured in collision with unspecified motor vehicles in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V29.091A	Electric (assisted) bicycle driver injured in collision with other motor vehicles in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.091D	Electric (assisted) bicycle driver injured in collision with other motor vehicles in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.091S	Electric (assisted) bicycle driver injured in collision with other motor vehicles in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V29.098A	Other motorcycle driver injured in collision with other motor vehicles in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.098D	Other motorcycle driver injured in collision with other motor vehicles in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.098S	Other motorcycle driver injured in collision with other motor vehicles in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V29.101A	Electric (assisted) bicycle passenger injured in collision with unspecified motor vehicles in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.101D	Electric (assisted) bicycle passenger injured in collision with unspecified motor vehicles in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.101S	Electric (assisted) bicycle passenger injured in collision with unspecified motor vehicles in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V29.108A	Other motorcycle passenger injured in collision with unspecified motor vehicles in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.108D	Other motorcycle passenger injured in collision with unspecified motor vehicles in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.108S	Other motorcycle passenger injured in collision with unspecified motor vehicles in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V29.191A	Electric (assisted) bicycle passenger injured in collision with other motor vehicles in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.191D	Electric (assisted) bicycle passenger injured in collision with other motor vehicles in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.191S	Electric (assisted) bicycle passenger injured in collision with other motor vehicles in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V29.198A	Other motorcycle passenger injured in collision with other motor vehicles in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.198D	Other motorcycle passenger injured in collision with other motor vehicles in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.198S	Other motorcycle passenger injured in collision with other motor vehicles in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V29.201A	Unspecified electric (assisted) bicycle rider injured in collision with unspecified motor vehicles in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.201D	Unspecified electric (assisted) bicycle rider injured in collision with unspecified motor vehicles in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.201S	Unspecified electric (assisted) bicycle rider injured in collision with unspecified motor vehicles in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V29.208A	Unspecified rider of other motorcycle injured in collision with unspecified motor vehicles in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.208D	Unspecified rider of other motorcycle injured in collision with unspecified motor vehicles in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.208S	Unspecified rider of other motorcycle injured in collision with unspecified motor vehicles in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V29.291A	Unspecified electric (assisted) bicycle rider injured in collision with other motor vehicles in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.291D	Unspecified electric (assisted) bicycle rider injured in collision with other motor vehicles in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.291S	Unspecified electric (assisted) bicycle rider injured in collision with other motor vehicles in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V29.298A	Unspecified rider of other motorcycle injured in collision with other motor vehicles in nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.298D	Unspecified rider of other motorcycle injured in collision with other motor vehicles in nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.298S	Unspecified rider of other motorcycle injured in collision with other motor vehicles in nontraffic accident, sequela	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V29.31XA	Electric (assisted) bicycle (driver) (passenger) injured in unspecified nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.31XD	Electric (assisted) bicycle (driver) (passenger) injured in unspecified nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.31XS	Electric (assisted) bicycle (driver) (passenger) injured in unspecified nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V29.39XA	Other motorcycle (driver) (passenger) injured in unspecified nontraffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.39XD	Other motorcycle (driver) (passenger) injured in unspecified nontraffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.39XS	Other motorcycle (driver) (passenger) injured in unspecified nontraffic accident, sequela	INFORMATIONAL DIAGNOSES
V29.401A	Electric (assisted) bicycle driver injured in collision with unspecified motor vehicles in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.401D	Electric (assisted) bicycle driver injured in collision with unspecified motor vehicles in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.401S	Electric (assisted) bicycle driver injured in collision with unspecified motor vehicles in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V29.408A	Other motorcycle driver injured in collision with unspecified motor vehicles in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.408D	Other motorcycle driver injured in collision with unspecified motor vehicles in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.408S	Other motorcycle driver injured in collision with unspecified motor vehicles in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V29.491A	Electric (assisted) bicycle driver injured in collision with other motor vehicles in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.491D	Electric (assisted) bicycle driver injured in collision with other motor vehicles in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.491S	Electric (assisted) bicycle driver injured in collision with other motor vehicles in traffic accident, sequela	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V29.498A	Other motorcycle driver injured in collision with other motor vehicles in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.498D	Other motorcycle driver injured in collision with other motor vehicles in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.498S	Other motorcycle driver injured in collision with other motor vehicles in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V29.501A	Electric (assisted) bicycle passenger injured in collision with unspecified motor vehicles in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.501D	Electric (assisted) bicycle passenger injured in collision with unspecified motor vehicles in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.501S	Electric (assisted) bicycle passenger injured in collision with unspecified motor vehicles in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V29.508A	Other motorcycle passenger injured in collision with unspecified motor vehicles in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.508D	Other motorcycle passenger injured in collision with unspecified motor vehicles in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.508S	Other motorcycle passenger injured in collision with unspecified motor vehicles in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V29.591A	Electric (assisted) bicycle passenger injured in collision with other motor vehicles in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.591D	Electric (assisted) bicycle passenger injured in collision with other motor vehicles in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.591S	Electric (assisted) bicycle passenger injured in collision with other motor vehicles in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V29.598A	Other motorcycle passenger injured in collision with other motor vehicles in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.598D	Other motorcycle passenger injured in collision with other motor vehicles in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V29.598S	Other motorcycle passenger injured in collision with other motor vehicles in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V29.601A	Unspecified electric (assisted) bicycle rider injured in collision with unspecified motor vehicles in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.601D	Unspecified electric (assisted) bicycle rider injured in collision with unspecified motor vehicles in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.601S	Unspecified electric (assisted) bicycle rider injured in collision with unspecified motor vehicles in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V29.608A	Unspecified rider of other motorcycle injured in collision with unspecified motor vehicles in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.608D	Unspecified rider of other motorcycle injured in collision with unspecified motor vehicles in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.608S	Unspecified rider of other motorcycle injured in collision with unspecified motor vehicles in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V29.691A	Unspecified electric (assisted) bicycle rider injured in collision with other motor vehicles in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.691D	Unspecified electric (assisted) bicycle rider injured in collision with other motor vehicles in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.691S	Unspecified electric (assisted) bicycle rider injured in collision with other motor vehicles in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V29.698A	Unspecified rider of other motorcycle injured in collision with other motor vehicles in traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.698D	Unspecified rider of other motorcycle injured in collision with other motor vehicles in traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V29.698S	Unspecified rider of other motorcycle injured in collision with other motor vehicles in traffic accident, sequela	INFORMATIONAL DIAGNOSES
V29.811A	Electric (assisted) bicycle rider (driver) (passenger) injured in transport accident with military vehicle, initial encounter	INFORMATIONAL DIAGNOSES
V29.811D	Electric (assisted) bicycle rider (driver) (passenger) injured in transport accident with military vehicle, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.811S	Electric (assisted) bicycle rider (driver) (passenger) injured in transport accident with military vehicle, sequela	INFORMATIONAL DIAGNOSES
V29.818A	Rider (driver) (passenger) of other motorcycle injured in transport accident with military vehicle, initial encounter	INFORMATIONAL DIAGNOSES
V29.818D	Rider (driver) (passenger) of other motorcycle injured in transport accident with military vehicle, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.818S	Rider (driver) (passenger) of other motorcycle injured in transport accident with military vehicle, sequela	INFORMATIONAL DIAGNOSES
V29.881A	Electric (assisted) bicycle rider (driver) (passenger) injured in other specified transport accidents, initial encounter	INFORMATIONAL DIAGNOSES
V29.881D	Electric (assisted) bicycle rider (driver) (passenger) injured in other specified transport accidents, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.881S	Electric (assisted) bicycle rider (driver) (passenger) injured in other specified transport accidents, sequela	INFORMATIONAL DIAGNOSES
V29.888A	Rider (driver) (passenger) of other motorcycle injured in other specified transport accidents, initial encounter	INFORMATIONAL DIAGNOSES
V29.888D	Rider (driver) (passenger) of other motorcycle injured in other specified transport accidents, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.888S	Rider (driver) (passenger) of other motorcycle injured in other specified transport accidents, sequela	INFORMATIONAL DIAGNOSES
V29.91XA	Electric (assisted) bicycle rider (driver) (passenger) injured in unspecified traffic accident, initial encounter	INFORMATIONAL DIAGNOSES

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ICD10 Code	Code Description	Recommended Placement
V29.91XD	Electric (assisted) bicycle rider (driver) (passenger) injured in unspecified traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.91XS	Electric (assisted) bicycle rider (driver) (passenger) injured in unspecified traffic accident, sequela	INFORMATIONAL DIAGNOSES
V29.99XA	Rider (driver) (passenger) of other motorcycle injured in unspecified traffic accident, initial encounter	INFORMATIONAL DIAGNOSES
V29.99XD	Rider (driver) (passenger) of other motorcycle injured in unspecified traffic accident, subsequent encounter	INFORMATIONAL DIAGNOSES
V29.99XS	Rider (driver) (passenger) of other motorcycle injured in unspecified traffic accident, sequela	INFORMATIONAL DIAGNOSES
W23.2XXA	Caught, crushed, jammed or pinched between a moving and stationary object, initial encounter	INFORMATIONAL DIAGNOSES
W23.2XXD	Caught, crushed, jammed or pinched between a moving and stationary object, subsequent encounter	INFORMATIONAL DIAGNOSES
W23.2XXS	Caught, crushed, jammed or pinched between a moving and stationary object, sequela	INFORMATIONAL DIAGNOSES
Z03.83	Encounter for observation for suspected conditions related to home physiologic monitoring device ruled out	DIAGNOSTIC WORKUP FILE (DWF)
Z28.310^	Unvaccinated for COVID-19	INFORMATIONAL DIAGNOSES
Z28.311^	Partially vaccinated for COVID-19	INFORMATIONAL DIAGNOSES
Z28.39^	Other underimmunization status	INFORMATIONAL DIAGNOSES
Z59.82	Transportation insecurity	INFORMATIONAL DIAGNOSES
Z59.86	Financial insecurity	INFORMATIONAL DIAGNOSES
Z59.87	Material hardship	INFORMATIONAL DIAGNOSES
Z71.87	Encounter for pediatric-to-adult transition counseling	DIAGNOSTIC WORKUP FILE (DWF)
Z71.88	Encounter for counseling for socioeconomic factors	DIAGNOSTIC WORKUP FILE (DWF)
Z72.823	Risk of suffocation (smothering) under another while sleeping	INFORMATIONAL DIAGNOSES
Z79.60	Long term (current) use of unspecified immunomodulators and immunosuppressants	DIAGNOSTIC WORKUP FILE (DWF)
Z79.61	Long term (current) use of immunomodulator	DIAGNOSTIC WORKUP FILE (DWF)
Z79.620	Long term (current) use of immunosuppressive biologic	DIAGNOSTIC WORKUP FILE (DWF)

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Z79.621	Long term (current) use of calcineurin inhibitor	DIAGNOSTIC WORKUP FILE (DWF)
Z79.622	Long term (current) use of Janus kinase inhibitor	DIAGNOSTIC WORKUP FILE (DWF)
Z79.623	Long term (current) use of mammalian target of rapamycin (mTOR) inhibitor	DIAGNOSTIC WORKUP FILE (DWF)
Z79.624	Long term (current) use of inhibitors of nucleotide synthesis	DIAGNOSTIC WORKUP FILE (DWF)
Z79.630	Long term (current) use of alkylating agent	DIAGNOSTIC WORKUP FILE (DWF)
Z79.631	Long term (current) use of antimetabolite agent	DIAGNOSTIC WORKUP FILE (DWF)
Z79.632	Long term (current) use of antitumor antibiotic	DIAGNOSTIC WORKUP FILE (DWF)
Z79.633	Long term (current) use of mitotic inhibitor	DIAGNOSTIC WORKUP FILE (DWF)
Z79.634	Long term (current) use of topoisomerase inhibitor	DIAGNOSTIC WORKUP FILE (DWF)
Z79.64	Long term (current) use of myelosuppressive agent	DIAGNOSTIC WORKUP FILE (DWF)
Z79.69	Long term (current) use of other immunomodulators and immunosuppressants	DIAGNOSTIC WORKUP FILE (DWF)
Z79.85	Long-term (current) use of injectable non-insulin antidiabetic drugs	DIAGNOSTIC WORKUP FILE (DWF)
Z87.61	Personal history of (corrected) necrotizing enterocolitis of newborn	INFORMATIONAL DIAGNOSES
Z87.68	Personal history of other (corrected) conditions arising in the perinatal period	INFORMATIONAL DIAGNOSES
Z87.731	Personal history of (corrected) tracheoesophageal fistula or atresia	INFORMATIONAL DIAGNOSES
Z87.732	Personal history of (corrected) persistent cloaca or cloacal malformations	INFORMATIONAL DIAGNOSES
Z87.760	Personal history of (corrected) congenital diaphragmatic hernia or other congenital diaphragm malformations	INFORMATIONAL DIAGNOSES
Z87.761	Personal history of (corrected) gastroschisis	INFORMATIONAL DIAGNOSES
Z87.762	Personal history of (corrected) prune belly malformation	INFORMATIONAL DIAGNOSES
Z87.763	Personal history of other (corrected) congenital abdominal wall malformations	INFORMATIONAL DIAGNOSES
Z87.768	Personal history of other specified (corrected) congenital malformations of integument, limbs and musculoskeletal system	INFORMATIONAL DIAGNOSES

Appendix B
New Codes

ICD10 Code	Code Description	Recommended Placement
Z91.110	Patient's noncompliance with dietary regimen due to financial hardship	INFORMATIONAL DIAGNOSES
Z91.118	Patient's noncompliance with dietary regimen for other reason	INFORMATIONAL DIAGNOSES
Z91.119	Patient's noncompliance with dietary regimen due to unspecified reason	INFORMATIONAL DIAGNOSES
Z91.190	Patient's noncompliance with other medical treatment and regimen due to financial hardship	INFORMATIONAL DIAGNOSES
Z91.198	Patient's noncompliance with other medical treatment and regimen for other reason	INFORMATIONAL DIAGNOSES
Z91.199	Patient's noncompliance with other medical treatment and regimen due to unspecified reason	INFORMATIONAL DIAGNOSES
Z91.A10	Caregiver's noncompliance with patient's dietary regimen due to financial hardship	INFORMATIONAL DIAGNOSES
Z91.A18	Caregiver's noncompliance with patient's dietary regimen for other reason	INFORMATIONAL DIAGNOSES
Z91.A20	Caregiver's intentional underdosing of patient's medication regimen due to financial hardship	INFORMATIONAL DIAGNOSES
Z91.A28	Caregiver's intentional underdosing of medication regimen for other reason	INFORMATIONAL DIAGNOSES
Z91.A3	Caregiver's unintentional underdosing of patient's medication regimen	INFORMATIONAL DIAGNOSES
Z91.A4	Caregiver's other noncompliance with patient's medication regimen	INFORMATIONAL DIAGNOSES
Z91.A5	Caregiver's noncompliance with patient's renal dialysis	INFORMATIONAL DIAGNOSES
Z91.A9	Caregiver's noncompliance with patient's other medical treatment and regimen	INFORMATIONAL DIAGNOSES

Appendix C

New Guideline Notes

Effective 1/1/2024
GUIDELINE NOTE XXX INSOMNIA
Line 202
Insomnia is included on this line for pairing with cognitive behavioral therapy (CBT). Short term (up to 1 month per year) treatment with sedative-hypnotic medications is included on this line only if the patient is currently in CBT or has failed to respond to recent CBT (in the past year). Long-term (more than 1 month) treatment with sedative-hypnotic medications is not included on this line.

Effective 1/1/2023
GUIDELINE NOTE XXX PANDAS, PANS AND AUTOIMMUNE ENCEPHALITIS
Line 313
ICD-10-CM G04.81 (Other encephalitis and encephalomyelitis) is only included on this line for autoimmune encephalitis and related non-PANDAS/PANS conditions and is not included in this guideline. Autoimmune encephalitis must meet established diagnostic criteria (for example, the International Encephalitis Consortium 2013 diagnostic criteria).

Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) is included on this line when coded with ICD-10-CM D89.89 (Other specified disorders involving the immune mechanism, not elsewhere classified). Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) is included on this line when coded with ICD-10-CM D89.9 (Disorder involving the immune mechanism, unspecified).

Up to 3 monthly immunomodulatory courses of intravenous immunoglobulin (IVIG) therapy is included on this line to treat PANDAS and PANS when both of the following are met:

a) A clinically appropriate trial of two or more less-intensive treatments (for example, appropriate limited course of nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, selective serotonin reuptake inhibitors (SSRIs), behavioral therapy, short-course antibiotic therapy) was either not effective, not tolerated, or did not result in sustained improvement in symptoms (as measured by a lack of clinically meaningful improvement on a validated instrument directed at the patient's primary symptom complex). These trials may be done concurrently, AND
b) A consultation with and recommendation from a pediatric subspecialist (for example, pediatric neurologist, pediatric psychiatrist, neurodevelopmental pediatrician, pediatric rheumatologist, pediatric allergist/immunologist) as well as the recommendation of the patient's primary care provider (for example, family physician, pediatrician, pediatric nurse practitioner, naturopath). The subspecialist consultation may be a teleconsultation. For adolescents, an adult subspecialist consult may replace a pediatric subspecialist consult.

A reevaluation at 3 months by both the primary care provider and pediatric expert is required for continued therapy of IVIG. This evaluation must include clinical testing with a validated instrument, which must be performed pretreatment and posttreatment to demonstrate clinically meaningful improvement. Long term antibiotic therapy is not included on this line for treatment of PANDAS/PANS. Therapeutic plasma exchange (CPT 36514) does not pair with PANDAS or PANS (ICD-10-CM D89.89 or D89.9).

Appendix C

Effective 1/1/2023

GUIDELINE NOTE XXX HIGH-FREQUENCY CHEST WALL OSCILLATION DEVICES

Lines 20, 58, 71, 197

High-frequency chest wall oscillation devices are included on these lines ONLY when:

A) The patient has cystic fibrosis, AND
   1) There is documentation of frequent exacerbations requiring antibiotics, frequent hospitalization, OR rapidly declining lung function measured by spirometry, despite either:
      a) receiving chest physiotherapy and positive expiratory pressure therapy, OR
      b) documentation that chest physiotherapy and positive expiratory pressure devices are not tolerated or not available (e.g., inability of a caregiver to perform chest physiotherapy); OR

B) The patient has non-cystic fibrosis bronchiectasis AND the four criteria below are all met:
   1) The bronchiectasis is confirmed by computed tomography (CT) scan, AND
   2) There is evidence of chronic lung infection, AND
   3) The patient has experienced either:
      a) daily productive cough for at least 6 continuous months, OR
      b) frequent (> 2 times a year) exacerbations requiring antibiotic therapy, AND
   4) The patient has received chest physiotherapy and positive expiratory pressure therapy OR chest physiotherapy and positive expiratory pressure devices are not tolerated, contraindicated, or not available (e.g., inability of a caregiver to perform chest physiotherapy); OR

C) The patient has neuromuscular disease resulting in chronic lung disease when there is evidence of chronic lung infection, despite either:
   1) receiving chest physiotherapy and positive expiratory pressure therapy, OR
   2) documentation that chest physiotherapy and positive expiratory pressure devices are not tolerated, contraindicated, or not available (e.g., inability of a caregiver to perform chest physiotherapy).

Section 2.0

Staff Report

Section 3.0

Consent Agenda-

Straightforward Items

Consent Agenda Issues—October 2022

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
Z69.021 Z69.12 Z69.82	Encounter for mental health services for perpetrator of non-parental child abuse Encounter for mental health services for perpetrator of spousal or partner abuse Encounter for mental health services for perpetrator of other abuse	120 ABUSE AND NEGLECT	The Oregon Youth Authority has requested that these codes be added to a covered line to allow treatment of perpetrators of abuse, which is currently being paid out of general funds. A similar code (Z69.011 Encounter for mental health services for perpetrator of parental child abuse) is on line 120. The Z69 codes listed here are currently on the INFORMATIONAL FILE	Add Z69.021, Z69.12 and Z69.82 to line 120

Straightforward Guideline Note Changes
October 2022

1) The coding for fat grafting for breast augmentation was changed by CMS effective January 1, 2021. The current gender dysphoria guideline has a deleted CPT code included in it, as does not include the new, recommended CPT codes.
    a. Deleted code: CPT 19324 Mammaplasty, augmentation; without prosthetic implant
    b. Recommended replacement CPT: 15771 and 15772 (Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs)

    HERC staff recommendations
        1. Add CPT 15771 and 15772 (Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs) to line 312 GENDER DYSPHORIA/TRANSEXUALISM
        2. Modify GN 127 as shown below

GUIDELINE NOTE 127, GENDER DYSPHORIA

Line 312

Hormone treatment with GnRH analogues for delaying the onset of puberty and/or continued pubertal development is included on this line for gender questioning children and adolescents. This therapy should be initiated at the first physical changes of puberty, confirmed by pubertal levels of estradiol or testosterone, but no earlier than Tanner stages 2-3. Prior to initiation of puberty suppression therapy, adolescents must fulfill eligibility and readiness criteria and must have a comprehensive mental health evaluation. Ongoing psychological care is strongly encouraged for continued puberty suppression therapy.

Cross-sex hormone therapy is included on this line for treatment of adolescents and adults with gender dysphoria who meet appropriate eligibility and readiness criteria. To qualify for cross-sex hormone therapy, the patient must:

A) have persistent, well-documented gender dysphoria
B) have the capacity to make a fully informed decision and to give consent for treatment
C) have any significant medical or mental health concerns reasonably well controlled
D) have a comprehensive mental health evaluation provided in accordance with Version 7 of the World Professional Association for Transgender Health (WPATH) Standards of Care (www.wpath.org).

Sex reassignment surgery is included for patients who are sufficiently physically fit and meet eligibility criteria. To qualify for surgery, the patient must:

A) have persistent, well documented gender dysphoria
B) for genital surgeries, have completed twelve months of continuous hormone therapy as appropriate to the member's gender goals unless hormones are not clinically indicated for the individual
C) have completed twelve months of living in a gender role that is congruent with their gender identity unless a medical and a mental health professional both determine that this requirement is not safe for the patient
D) have the capacity to make a fully informed decision and to give consent for treatment
E) have any significant medical or mental health concerns reasonably well controlled
F) for breast/chest surgeries, have one referral from a mental health professional provided in accordance with version 7 of the WPATH Standards of Care.

G) For genital surgeries, have two referrals from mental health professionals provided in accordance with version 7 of the WPATH Standards of Care.

Electrolysis (CPT 17380) and laser hair removal (CPT 17110,17111) are only included on this line as part of pre-surgical preparation for chest or genital surgical procedures also included on this line. These procedures are not included on this line for facial or other cosmetic procedures or as pre-surgical preparation for a procedure not included on this line.

Mammoplasty (CPT 15771, 15772, 19316, ~~19324~~ 19325, 19340, 19342, 19350) is only included on this line when 12 continuous months of hormonal (estrogen) therapy has failed to result in breast tissue growth of Tanner Stage 5 on the puberty scale OR there is any contraindication to, intolerance of or patient refusal of hormonal therapy.

Revisions to surgeries for the treatment of gender dysphoria are only covered in cases where the revision is required to address complications of the surgery (wound dehiscence, fistula, chronic pain directly related to the surgery, etc.). Revisions are not covered solely for cosmetic issues.

Pelvic physical therapy (CPT 97110,97140,97161-97164, and 97530) is included on this line only for pre- and post-operative therapy related to genital surgeries also included on this line and as limited in Guideline Note 6 REHABILITATIVE AND HABILITATIVE THERAPIES.

2) GN 154 has confusing wording in it that staff recommends removing.

HERC staff recommendation:

1. Modify GN154 as shown below

GUIDELINE NOTE 154, EAR DRUM REPAIR

Lines 311,446,476

Repair of open wounds or perforations of the ear drum (~~codes included on these lines from~~ ICD-10-CM H72~~,~~ and S09.2) are only included on Lines 311 and 446 when there is documented conductive hearing loss greater than or equal to 25dB persistent for more than three months. Otherwise, such repairs are included on Line 476 CHRONIC OTITIS MEDIA; OPEN WOUND OF EAR DRUM.

3) Guideline Note 24 COMPLICATED HERNIAS needs a clarifying sentence added to specify that inguinal and femoral hernias in men are intended to be on line 524 if they do not meet criteria for line 168.
    a. HERC staff recommendation: modify GN24 as shown below

GUIDELINE NOTE 24, COMPLICATED HERNIAS

Lines 168,524

Complicated inguinal and femoral hernias in men are included on Line 168 if the hernia

A) Causes symptoms of intestinal obstruction and/or strangulation; OR

B) Is incarcerated (defined as non-reducible by physical manipulation); OR
C) Causes pain and functional limitations as assessed and documented by a medical professional; OR
D) Affects the patient's ability to obtain or maintain gainful employment.

Otherwise, inguinal and femoral hernias in men are included on line 524.

Repair of inguinal and femoral hernias in women and in children age 18 or younger are included on Line 168 due to the different natural history of disease in these populations.

Ventral hernias are included on Line 524. Incarcerated ventral hernias (including incarcerated abdominal incisional and umbilical hernias) are included on Line 524, because the chronic incarceration of large ventral hernias does not place the patient at risk for impending strangulation. Ventral hernias are defined as anterior abdominal wall hernias and include primary ventral hernias (epigastric, umbilical, Spigelian), paratomal hernias and most incisional hernias (ventral incisional hernias). ICD-10-CM K42.0, K43.0, K43.3, K43.6 and K46.0 are included on Line 524 when used to designate incarcerated abdominal incisional and umbilical hernias without intestinal obstruction or gangrene.

4) A number of errors were found in the October 2021 changes made for coverage of complications from circumcision. In the meeting materials, several incorrect line references were given. The CPT codes for repair of post-circumcision adhesions were noted to be on line 572 OTHER COMPLICATIONS OF A PROCEDURE, when they are actually on line 573 REDUNDANT PREPUCE. The guideline incorrectly was updated with an incorrect line number (571) referencing the line titled "OTHER COMPLICATIONS OF A PROCEDURE." However, the guideline should actually be attached to line 573. In addition, the line number for the covered complications line was not updated with the new Prioritized List line number.
    a. HERC staff recommendations:
        i. Add ICD-10-CM T81.9XXA (Unspecified complication of procedure, initial encounter) to line 573 REDUNDANT PREPUCE
        ii. Modify GN73 as shown below

GUIDELINE NOTE 73, PENILE ANOMALIES

Lines 424,~~433~~ 434,~~571~~,573, 658

Congenital anomalies of the penis (ICD-10-CM Q54.4, Q55.5 and Q55.6) are included on Line 434 only when they

A. Are associated with hypospadias, OR
B. Result in documented urinary retention, OR
C. Result in repeated urinary tract infections, OR
D. Result in recurrent infections such as meatitis or balanitis, OR
E. Involve 35 degrees of curvature or greater for conditions resulting in lateral or ventral curvature, OR
F. Involve 60 degrees of rotation or greater for conditions resulting in penile torsion, OR
G. Involve aplasia/congenital absence of the penis.

Otherwise, these diagnoses are included on Line 658

Acquired anomalies of the penis (ICD-10-CM N48.82, N48.83, N48.89 or T81.9XXA) are included on Line 424 only when they are the result of a prior penile procedure AND either

A. Result in a skin bridge, OR

B. Result in a buried penis, OR

C. Are associated with hypospadias, OR

D. Result in documented urinary retention, OR

E. Result in repeated urinary tract infections, OR

F. Result in recurrent infections such as meatitis or balanitis, OR

G. Involve 35 degrees of curvature or greater for conditions resulting in lateral or ventral curvature, OR

H. Involve 60 degrees of rotation or greater for conditions resulting in penile torsion.

Otherwise, these diagnoses are included on Line ~~571~~ 573 or Line 658.

COVID-19 Related Codes
October 2022

Issues:

1) New COVID vaccine codes were released for the new bivalent Pfizer—BioNTech booster and the new bivalent Moderna booster
    a. Note: the booster doses for children have not yet received FDA EUA

HERC staff recommendations:

1) Add the following CPT codes to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS

CPT Code	**Code Description**
91313	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, bivalent, preservative free, 50 mcg/0.5 mL dosage, for intramuscular use Moderna bivalent booster for 18 yrs and older
0134A	Moderna bivalent booster for 18 yrs and older administration
91314	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, bivalent, preservative free, 25 mcg/0.25 mL dosage, for intramuscular use Moderna bivalent booster for 6-11 years
0144A	Moderna bivalent booster for 6-11 years administration
91312	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, bivalent spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation, for intramuscular use Pfizer-BioNTech bivalent booster for 12 yrs and older
0124A	Pfizer-BioNTech bivalent booster for 12 yrs and older administration
91315	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, bivalent spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for intramuscular use Pfizer-BioNTech bivalent booster for 5-11 yrs
0154A	Pfizer-BioNTech bivalent booster for 5-11 yrs administration

Section 4.0

BHAP report

Highlights

Behavioral Health Advisory Panel
Online meeting
September 7, 2022
9:00 am--11:00 am

Members Present: Kathy Savicki, LCSW; Sheldon Levy, PhD

Members Absent: Lynnea Lindsey, PhD Chair; Gary Cobb; Eric Davis, MSW, CADC III, PSS; MSCP; John Bischof, MD.

Staff Present: Ariel Smits, MD, MPH; Liz Walker, MPH; Daphne Peck

Also Attending: Luke Todd, Heather Uerlings, Andrew Gibler, Roger Citron and Amy Gordon (OHA), Megan Wai (Sen. Patterson's office), Jessica Casato, Jennifer Peer, Steph Baer, Ryan Bair (AllCare Health), Abbey Collins, Danielle Wright Elders, Molly Taylor, Lindsey Phillips, Barbara Scaturro, Lisa Ashton, Erin Porter, Chris Potters, Amelia Harju, tansmith, Tami Stump (Polk County), Alexis Henry

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1. CALL TO ORDER

The meeting was called to order at 9:08 am. The highlights from the July 25, 2022 BHAP meeting were reviewed and no changes or edits were recommended.

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2. PRIORITIZED LIST ISSUES

1) Residential therapy for anxiety:
   There was minimal discussion. Panel members agreed with staff recommendations.

2) Acupuncture guideline update for SUD therapy:
   Savicki questioned whether there was evidence for acupuncture not in a formal treatment plan, and who would co-ordinate the therapy. The discussion was that the provider would need to document of other treatment modalities in place to allow coverage of the acupuncture. The proposal was changed to include the word "documented" before "broader treatment plan."

3) Prioritization of personality disorders:
   There was minimal discussion. Panel members agreed with staff recommendations.

4) Somatic symptoms:
   Savicki noted that these conditions should have a consultation with a behavioral health provider to give assistance to the physical health provider. Dr. Levy noted that these patients tend to

have a behavioral health provider in primary care homes. Panel members agreed with staff recommendations.

5) Clubhouse services:
   Savicki noted that she generally supports peer-support services, but wonders about what criteria would be in place to define a quality Clubhouse. There were also concerns about who can bill for this, as there would be no diagnostic code and no professional provider. Levy asked what the funding was needed for. Savicki responded that there is paid peer staff and building overhead. Savicki supported putting this code on the Prioritized list to allow a pilot. Levy suggested that these HCPCS code be placed on all lines with group psychotherapy, as this is the closest model to a Clubhouse. Members were supportive of a pilot program to clarify the implementation issues. Savicki noted that Clubhouse services are less expensive that active therapy. Savicki and Levy noted that patients who choose to participate in Clubhouse services are self-selected. There was discussion about adding a guideline if needed to define what is a clubhouse if needed after a pliot study is completed.

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3. ADJOURNMENT

The meeting was adjourned at 9:45 AM.

Residential Therapy for Anxiety

Plain Language Summary:
Background: Should short or medium-term therapy given in a residential setting be covered on the anxiety line? Currently, long-term therapy is covered for anxiety, and short- or medium-term therapy is not covered. Oregon Health Authority requested these also be covered.

Should OHP cover this treatment? Staff recommends cover this treatment because these codes are already on other Prioritized List lines are like the long-term codes. Additionally, similar mental health conditions have short, medium and long-term therapy covered.

Question: Should short- and medium-term residential therapy be paired with generalized anxiety disorder (GAD)?

Question source: HSD/Claims

Issue: Currently, long-term residential therapy is on the generalized anxiety line, but not short- or medium-term residential therapy. HSD Claims Reconciliation is requesting that these other residential therapies codes be paired with GAD on the anxiety line.

Current Prioritized List status:

Line 414 OVERANXIOUS DISORDER; GENERALIZED ANXIETY DISORDER; ANXIETY DISORDER, UNSPECIFIED
ICD-10-CM F41.1 Generalized anxiety disorder

HCPCS H0019 Behavioral health; long-term residential (non-medical, non-acute care in a residential treatment program where stay is typically longer than 30 days), without room and board, per diem
On all BH lines including 414

H0017 Behavioral health; residential (hospital residential treatment program), without room and board, per diem
On many other BH lines, but NOT 414

H0018 Behavioral health; short-term residential (non-hospital residential treatment program), without room and board, per diem
On many other BH lines, but NOT 414

BHAP input:
BHAP members unanimously agreed with the recommended change

HERC staff recommendation

1) Add HCPCS H0017 (Behavioral health; residential (hospital residential treatment program), without room and board, per diem) and H0018 (Behavioral health; short-term residential (non-hospital residential treatment program), without room and board, per diem) to line 414 OVERANXIOUS DISORDER; GENERALIZED ANXIETY DISORDER; ANXIETY DISORDER, UNSPECIFIED

Acupuncture Guideline Clarification Regarding SUD Treatment

Plain Language Summary:
Background: The acupuncture guideline for substance use disorders (SUD) may be unclear. Some CCOs require patients to be enrolled in a *formal* treatment program, which is not the Commission's aim. The intent is to make sure the patient is in some other type of SUD treatment but does not require it be a formal program.

Should OHP cover this treatment? Staff recommends editing this guideline to make it clear that enrollment in a formal treatment program is not required, but that other types of treatment must still be included in the treatment plan.

Question: Should the acupuncture guideline be updated to clarify when acupuncture is covered for SUD treatment?

Question source: Laura Ocker, LAc

Issue: The acupuncture guideline allows a limited number of visits for substance use disorder (SUD) therapy when a patient is receiving other SUD therapy services. The evidence review of acupuncture for SUD therapy found that it was helpful as an adjunctive therapy, but not as a sole therapy for SUD. Laura Ocker has encountered at least one CCO that is requiring a patient to be in a structured SUD treatment program. The intent of the guideline was to require that the patient be receiving other SUD treatments in addition to acupuncture, but not necessarily be in a structured treatment program.

BHAP input:
There was some concern about acupuncture not being part of a larger treatment plan, and how a CCO would know that a patient is getting other services. The panel suggested adding "documented" to "broader treatment plan" to ensure that there is some documentation forwarded to the CCO regarding other treatments being utilized.

HERC staff recommendation:
1) Modify GN92 as shown below

GUIDELINE NOTE 92, ACUPUNCTURE

Lines 1,4,5,64,65,92,111,112,114,125,129,133,135,157,158,191,199-201,208,210,214,215,229,234, 237,238,258,259,262,271,276,286,287,294,314-316,329,342,361,396,397,402,410,419,435,464,541, 559

Inclusion of acupuncture (CPT 97810-97814) on the Prioritized List has the following limitations:

Line 1 PREGNANCY
Acupuncture pairs on Line 1 for the following conditions and codes.
Hyperemesis gravidarum
ICD-10-CM: O21.0, O21.1
Acupuncture pairs with hyperemesis gravidarum when a diagnosis is made by the maternity care provider and referred for acupuncture treatment for up to 12 sessions of acupressure/acupuncture per pregnancy.
Breech presentation

ICD-10-CM: O32.1

Acupuncture (and moxibustion) is paired with breech presentation when a referral with a diagnosis of breech presentation is made by the maternity care provider, the patient is between 33 and 38 weeks gestation, for up to 6 session per pregnancy.

Back and pelvic pain of pregnancy

ICD-10-CM: O99.89

Acupuncture is paired with back and pelvic pain of pregnancy when referred by maternity care provider/primary care provider for up to 12 sessions per pregnancy.

Line 4 SUBSTANCE USE DISORDER,Line 62 SUBSTANCE-INDUCED MOOD, ANXIETY, DELUSIONAL AND OBSESSIVE-COMPULSIVE DISORDERS,Line 65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL

Acupuncture is included on these lines only when used as part of a ~~program~~ documented broader treatment plan that offers patients a variety of evidence-based interventions including behavioral interventions, social support, and Medication Assisted Treatment (MAT), as appropriate.

Line 5 TOBACCO DEPENDENCE

Acupuncture is included on this line for a maximum of 12 sessions per quit attempt up to two quit attempts per year; additional sessions may be authorized if medically appropriate.

Lines 92, 111, 112, 114, 125, 129, 133, 135, 157, 158, 191, 199, 200, 208, 210, 214, 215, 229, 234, 237, 238, 258, 259, 261, 262, 271, 276, 286, 287, 294, 314, 315, 316, 329, 342, 372, 396, 397, 419, 435 and 559

Acupuncture is paired only with the ICD-10 code G89.3 (Neoplasm related pain (acute) (chronic)) when there is active cancer and limited to 12 total sessions per year; patients may have additional visits authorized beyond these limits if medically appropriate.

Line 201 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS

Acupuncture is paired with the treatment of post-stroke depression only. Treatments may be billed to a maximum of 30 minutes face-to-face time and limited to 12 total sessions per year, with documentation of meaningful improvement; patients may have additional visits authorized beyond these limits if medically appropriate.

Line 361 SCOLIOSIS

Acupuncture is included on this line with visit limitations as in Guideline Note 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE.

Line 402 CONDITIONS OF THE BACK AND SPINE

Acupuncture is included on this line with visit limitations as in Guideline Note 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE.

Line 410 MIGRAINE HEADACHES

Acupuncture pairs on Line 410 for migraine (ICD-10-CM G43.0, G43.1, G43.5, G43.7, G43.8, G43.9), for up to 12 sessions per year.

Line 464 OSTEOARTHRITIS AND ALLIED DISORDERS

Acupuncture pairs on Line 464 for osteoarthritis of the knee only (ICD-10-CM M17), for up to 12 sessions per year.

*Line 541 TENSION HEADACHES

Acupuncture is included on Line 541 for treatment of tension headaches (ICD-10-CM G44.2), for up to 12 sessions per year.

The development of this guideline note was informed by a HERC coverage guidance. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx

*Below the current funding line.

Somatization, Conversion Disorder, Hypochondriasis, Factitious Disorder and Related Conditions

Question: Should some or all of the conditions related to somatization be given a higher priority?

Question source: HERC staff; Below the Line Review

Issue: Somatization, conversion disorder, hypochondriasis, factitious disorder and related conditions are currently on line 552 SOMATIC SYMPTOMS AND RELATED DISORDERS. As part of the Below the Line review, staff have reviewed these conditions and the effectiveness of their treatment for consideration for possible re-prioritization. Somatization and related disorders are a group of conditions which have traditionally been considered difficult to treat.

On review of line 552, F44.0-F44.2 (Dissociative disorder) was found to also be on line 407 DISSOCIATIVE DISORDERS with no guideline regarding when the diagnoses were on the covered line. Body dysmorphic disorder (F45.22) was found to be on line 463 OBSESSIVE-COMPULSIVE DISORDERS as well as line 552 with no guideline. ICD-10-CM F45.42 (Pain disorder with related psychological factors) was found to be on lines 402 and 552.

HSC/HERC history

Somatization disorder was a funded diagnosis until 2014, when the somatization line was merged with the factitious disorders line. This change was made as part of the ICD-10 conversion review. The new line was re-prioritized and moved to a much lower priority position. The line scoring included a downgrading of the condition category from category 6 to category 7 as it was not felt to be a fatal condition. Effectiveness of treatment was given a 1. There did not appear to be a literature review accompanying this recommendation; it was based on expert opinion.

Conditions and evidence of treatment effectiveness:

1) Conversion disorder
    a. Definition: also known as functional neurologic disorder (FND). A condition in which a patient presents with neurological symptoms, such as seizures or inability to move a limb, with no physical basis found.
    b. Evidence of effectiveness of treatment
        i. Aybek 2022:
            1. PT: based on a 2013 systematic review of 29 cohort studies and two more recent RCTs, PT was shown to improve quality of life and improve symptoms as well as improve physical and social functioning
            2. Psychotherapy: In several RCTs, psychotherapy was not found to have any lasting improvement on symptoms vs routine medical care
            3. Pharmacotherapy: selective serotonin reuptake inhibitors and serotonin norepinephrine reuptake inhibitors (or other indicted psychotropic medications) are used to manage concurrent mental health symptoms, but are not themselves indicated for the direct treatment of FND.
2) Somatization
    a. Definition: Somatic symptom disorder is diagnosed when a person has excessive thoughts, feelings or behaviors related to the somatic symptoms or associated health concerns such as pain, weakness or shortness of breath, to a level that results in major distress and/or problems functioning.
    b. Evidence of effectiveness of treatment

i. **Koelen 2014**
    1. Psychotherapy:
        a. 9 studies with 588 patients found psychotherapy was more effective eat reducing physical symptoms than treatment as usual [TAU] (pooled effect size 0.80, SD 0.50-1.09 for psychotherapy; pooled effect size 0.31, SD 0.02-0.60) for TAU)
        b. 14 studies with 787 patients found psychotherapy was more effective than treatment as usual for psychological symptoms (pooled effect size 0.75, SD 0.57-0.92 for psychotherapy; pooled effect size 0.51, SD 0.19-0.83 for TAU)
        c. 12 studies with 535 patients found that psychotherapy was more effective for improving functional impairment vs TAU (pooled effect size 0.45, SD 0.28-0.62 for psychotherapy; pooled effect size 0.15, SD 0.00-0.30 for TAU)
        d. Conclusions: Pre- to post-therapy improvements were large for physical symptoms, medium to large for psychological symptoms and small to medium for functional impairment. For TAU, effect sizes were small for physical symptoms, medium for psychological symptoms and very small for functional impairment. The differences in effect size between psychotherapy and TAU were significant for physical symptoms and functional impairment. These findings suggest that psychotherapy is more effective than TAU in severe somatoform disorder, particularly in terms of reduction of physical symptoms and functional impairment

3) <u>Hypochondriasis</u>
    a. Definition: also referred to as health anxiety. Hypochondriasis is defined by preoccupation with the belief that one has, or could acquire, a serious illness, emanating from 'anxiety about the meaning, significance or cause' of their symptoms. This is accompanied by high anxiety about health and excessive health-related behaviors or maladaptive avoidance
    b. Evidence of effectiveness of treatment
        i. **Kroenke 2007**:
            1. CBT proved consistently effective (four of four trials involving a total of 345 patients)
        ii. **Cooper 2017**:
            1. Systematic review of 14 studies (1544 patients)
            2. A meta-analysis of the overall effect of CBT on health anxiety outcome scores, compared with all control conditions (21 comparisons: active therapy, wait-list, TAU, medication and placebo medication) was conducted, resulting in a large mean effect size of d = 1.01 (95% CI (0.77–1.25). At 6-month follow-up (seven comparisons), a large effect size was again found (d = 0.91, 95% CI 0.39–1.44).
            3. Conclusions: This systematic review and meta-analysis provides support for the hypothesis that CBT is an effective intervention for HA when compared with a variety of control conditions, e.g. treatment-as-usual, waiting list, medication, and other psychological therapies.

4) <u>Factitious disorder</u>

a. Definition: a syndrome in which patients consciously induce, feign, or exaggerate physical or psychiatric symptoms for primary gain
b. Evidence of effectiveness of treatment
    i. **Bass 2014**: published series show that three-quarters of the patients were confronted, but only one in six acknowledged that their illness was self-induced; 12% agreed to have psychiatric treatment, but the outcomes were not published. Recovery from chronic factitious disorder is rare and largely unknown because many patients understandably drop out of follow-up.

BHAP discussion:

Savicki noted that these conditions should have a consultation with a behavioral health provider to give assistance to the physical health provider. Dr. Levy noted that these patients tend to have a behavioral health provider in primary care homes. Panel members agreed with staff recommendations.

HERC staff summary

Somatization disorder has evidence that it is treatable by psychotherapy; however, a BHAP review in 2014 resulted in this condition being given its current low priority. Hypochondriasis has evidence that it can be effectively treated by psychotherapy; however, most patients are not amenable to treatment. Factitious disorder and conversion disorder have little evidence of effective treatments.

HERC staff have identified some housekeeping items related to this topic that need to be addressed.

HERC staff recommendations:

1) Housekeeping items
    a. Remove the following ICD-10-CM diagnoses from line 552 SOMATIC SYMPTOMS AND RELATED DISORDERS as they already appear on other covered lines
        i. F44.0 Dissociative amnesia
        ii. F44.1 Dissociative fugue
        iii. F44.2 Dissociative stupor
        iv. F44.81 Dissociative identity disorder
        v. F44.89 Other dissociative and conversion disorders
        vi. F45.22 Body dysmorphic disorder
        vii. F45.42 Pain disorder with related psychological factors
    b. Remove ICD-10-CM F52.5 (Unspecified sexual dysfunction not due to a substance or known physiological condition) from line 552 SOMATIC SYMPTOMS AND RELATED DISORDERS and add to line 523 SEXUAL DYSFUNCTION
        i. More appropriate placement with similar diagnoses
2) Make no other changes to the prioritization of somatization disorder, hypochondriasis, factitious disorder and related conditions

Diagnosis and management of functional neurological disorder

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Series explanation: State of the Art Reviews are commissioned on the basis of their relevance to academics and specialists in the US and internationally. For this reason they are written predominantly by US authors.

ABSTRACT

Functional neurological disorder (FND), previously regarded as a diagnosis of exclusion, is now a rule-in diagnosis with available treatments. This represents a major step toward destigmatizing the disorder, which was often doubted and deemed untreatable. FND is prevalent, generally affecting young and middle aged adults, and can cause severe disability in some individuals. An early diagnosis, with subsequent access to evidence based rehabilitative and/or psychological treatments, can promote recovery—albeit not all patients respond to currently available treatments. This review presents the latest advances in the use of validated rule-in examination signs to guide diagnosis, and the range of therapeutic approaches available to care for patients with FND. The article focuses on the two most frequently identified subtypes of FND: motor (weakness and/or movement disorders) and seizure type symptoms. Twenty two studies on motor and 27 studies on seizure type symptoms report high specificities of clinical signs (64-100%), and individual signs are reviewed. Rehabilitative interventions (physical and occupational therapy) are treatments of choice for functional motor symptoms, while psychotherapy is an emerging evidence based treatment across FND subtypes. The literature to date highlights heterogeneity in responses to treatment, underscoring that more research is needed to individualize treatments and develop novel interventions.

Introduction

Historical background

Functional neurological disorder (FND) is a prevalent, costly, and potentially disabling condition encountered by healthcare professionals in medical, clinical neuroscience, and rehabilitative specialties.[1 2] The condition has a complex narrative in the literature that has benefited from and been hampered by the interwoven history of neurology and psychiatry.[3] Labeled medicine's "silent epidemic," a "crisis" in neurology, and psychiatry's "blind spot,"[4-6] FND has inspired renewed clinical and research interest during the past several decades. Important breakthroughs have included new diagnostic and therapeutic approaches to FND, as well as parallel advances in its pathophysiology. Figure 1 gives a brief overview of the emerging neurobiology of FND[7 8]—depicting the condition as characterized by dysfunction within and across several brain networks.

Nosological classification

FND is classified as "conversion disorder/functional neurological symptom disorder" in the chapter "Somatic Symptom and Related disorders, code F44.X" in the Diagnostic and Statistical Manual of Mental Disorders 5th Edition (DSM-5). In the ICD-11 (International Classification of Diseases), FND is classified as "dissociative neurological symptom disorder" in the chapter "Mental, Behavioural or Neurodevelopmental Disorders, code 6B60.X," as well as in the chapter "Diseases of the Nervous System, code 8A0X" under the term "movement disorder for parkinsonism, dystonia, and tremor" (see table 1 for details). This variability within and across classification systems is problematic, as it perpetuates a cartesian dualism and creates coding problems between mental health and neurological disorders that affect which clinical services will be reimbursed, or by which expert patients should be evaluated in medico-legal cases.

Aims of this review

In 2013, a new set of diagnostic criteria for FND appeared in the DSM-5, and emphasized the importance of making a rule-in positive diagnosis based on physical examination and semiological features. In the DSM-IV, emphasis was given to making an exclusionary diagnosis (based on all available neurological tests being normal) and

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Review article

Effectiveness of psychotherapy for severe somatoform disorder: meta-analysis

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Background
Patients with severe somatoform disorder (in secondary and tertiary care) typically experience functional impairment associated with physical symptoms and mental distress. Although psychotherapy is the preferred treatment, its effectiveness remains to be demonstrated.

Aims
To examine the effectiveness of psychotherapy for severe somatoform disorder in secondary and tertiary care compared with treatment as usual (TAU) but not waiting-list conditions.

Method
Main inclusion criteria were presence of a somatoform disorder according to established diagnostic criteria and receiving psychotherapy for somatoform disorder in secondary and tertiary care. Both randomised and non-randomised trials were included. The evaluated outcome domains were physical symptoms, psychological symptoms (depression, anxiety, anger, general symptoms) and functional impairment (health, life satisfaction, interpersonal problems, maladaptive cognitions and behaviour).

Results
Ten randomised and six non-randomised trials were included, comprising 890 patients receiving psychotherapy and 548 patients receiving TAU. Psychotherapy was more effective than TAU for physical symptoms ($d = 0.80$ *v.* $d = 0.31$, $P < 0.05$) and functional impairment ($d = 0.45$ *v.* $d = 0.15$, $P < 0.01$), but not for psychological symptoms ($d = 0.75$ *v.* $d = 0.51$, $P = 0.21$). These effects were maintained at follow-up.

Conclusions
Overall findings suggest that psychotherapy is effective in severe somatoform disorder. Future randomised controlled studies should examine specific interventions and mechanisms of change.

Declaration of interest
None.

Somatoform disorders are characterised by persistent physical symptoms that suggest the presence of a medical condition, but are not explained fully by that condition or by the direct effects of substance misuse or mental disorder (DSM-IV).[1] The prevalence of somatoform disorders is estimated at 6% in the general population.[2] Patients with such disorders usually have high functional impairment,[3,4] are difficult to treat,[5,6] and show high utilisation of medical care.[7] Moreover, it typically takes years before they are referred to mental healthcare.[6,8,9] A strictly somatic approach and unnecessary diagnostic examinations may increase somatising behaviours,[10] and lead to chronic symptoms and high medical costs:[7,11,12] these findings emphasise the need for early intervention.[13] Psychotherapy may be a viable treatment option given the role of behavioural, cognitive and emotional processes in these disorders and their high degree of comorbidity with mental disorders.[14–16] Some reviews and meta-analyses suggest that psychotherapy may be effective in patients with somatoform disorder.[17–19] However, these reviews were restricted to psychodynamic psychotherapy only,[17] or predominantly involved groups with less severe disorder, with functional neurological or conversion disorder generally being excluded.[18] Hypochondriasis and body dysmorphic disorder were typically included in these reviews,[19] although it is still a matter of debate whether these conditions should be classified as somatoform disorder.[14,20] The results of previous reviews cannot always be generalised to patients with strictly defined somatoform disorder in secondary and tertiary care, as these patients are generally more impaired than those seen in primary care.[21] Finally, previous meta-analyses typically included only randomised trials, often excluding effectiveness studies,[22–24] whereas the inclusion of both randomised and non-randomised studies allows the meta-analytic comparison of effect sizes between these designs.

The aim of our meta-analysis therefore was to examine the effectiveness of psychotherapy for patients with strictly defined, severe somatoform disorder treated in secondary and tertiary care. To that aim, we compared effect sizes from pre- to post-treatment and from post-treatment to follow-up of psychotherapy and treatment as usual, excluding waiting-list control groups. This study focused on pre- to post-treatment contrasts, and not on between-group contrasts, given the limited number of controlled treatment studies in this context. Given the small number of studies included, moderators of treatment effect were examined only exploratively. We examined methodological quality of the studies,[25] intervention characteristics (type, modality, frequency and length),[26] and whether treatment was offered in tertiary (multimodal and integrative) or secondary care settings,[18] as potential factors influencing treatment effectiveness.

Method

A multiple-phase search was conducted in March 2010 to retrieve as many studies as possible focusing on the effectiveness of psychological treatments of severe somatoform disorder. 'Severe' disorder was defined as a diagnosis of somatoform disorder according to established criteria and treatment offered in secondary or tertiary care settings. First, studies were retrieved from the Scopus and Web of Science databases with the following search terms: (somatoform* OR somatisation OR (conversion AND (disorder OR symptoms)) OR (somatoform* AND pain disorder) in the title AND (treatment OR therapy OR intervention OR outcome OR effect* OR efficacy OR evaluation) in the title, abstract or keywords. Second, the reference lists of previous reviews and meta-analyses were hand-searched for additional

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Efficacy of Treatment for Somatoform Disorders: A Review of Randomized Controlled Trials

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Objective: To review the evidence from randomized clinical trials (RCTs) that have focused on the treatment of patients with Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) somatoform disorders. Although somatoform disorders are among the most common mental disorders presenting in the general medical setting, the strength of evidence for specific treatments has not been well synthesized. **Methods:** MEDLINE search of articles published in English from 1966 to 2006, using the following search terms: randomized clinical trial, somatoform disorders, somatization disorder, undifferentiated somatoform disorder, hypochrondriasis, conversion disorder, pain disorder, and body dysmorphic disorder. **Results:** A total of 34 RCTs involving 3922 patients were included. Two thirds of the studies involved somatization disorder ($n = 4$ studies) and lower threshold variants, such as abridged somatization disorder ($n = 9$) and medically unexplained symptoms ($n = 10$). Cognitive behavioral therapy (CBT) was effective in most studies (11 of 13), as were antidepressants in a small number (4 of 5) of studies. RCTs examining a variety of other treatments showed benefit in half (8 of 16) of the studies, the most consistent evidence existing for a consultation letter to the primary care physician. Effective treatments have been established for all somatoform disorders except conversion disorder (1 of 3 studies showing benefit) and pain disorder (no studies reported). **Conclusion:** CBT is the best established treatment for a variety of somatoform disorders, with some benefit also demonstrated for a consultation letter to the primary care physician. Preliminary but not yet conclusive evidence exists for antidepressants. **Key words:** somatoform disorders, somatization, therapy, randomized controlled trials, review.

BDD = body dysmorphic disorder; **CBT** = cognitive behavioral therapy; **DSM-IV** = Diagnostic and Statistical Manual of Mental Disorders, 4th Edition; **PCP** = primary care physician; **RCT** = randomized clinical trial; **SD** = somatization disorder; **USD** = undifferentiated somatoform disorder.

INTRODUCTION

Somatoform disorders are among the most prevalent mental disorders seen in the general medical setting, present in 10% to 15% of primary care patients (1–4). The functional impairment associated with somatoform disorders is comparable with that seen in depressive and anxiety disorders (5,6). Moreover, clinically significant somatization leads to excessive health care use, costing the US health care system an estimated $100 billion annually (7). Also, somatoform disorders are among the most frustrating mental disorders for clinicians to manage and also result in high levels of patient dissatisfaction (5,8–10). Finally, there is greater skepticism regarding the treatability of somatoform disorders compared with the confidence practitioners have regarding the treatment of depression and anxiety. It is likely that if evidence-based treatments existed and were more uniformly applied, the adverse consequences of somatoform disorders, including disability, costs, and dissatisfaction would be reduced.

There have been several evidence-based reviews of psychological treatments for somatic symptoms and functional somatic syndromes (11–15). However, the overlap between these symptom-based general medical disorders and somatoform disorders remains controversial. Therefore, a critical review of the literature was undertaken to determine which treatments are efficacious for somatoform disorders and to ascertain the strength of evidence for particular treatments. The purpose is both to guide current practice as well as to identify gaps in the evidence to inform future treatment research.

METHODS

A MEDLINE search of articles published in English from 1966 to 2006 was conducted, using the following search terms: randomized clinical trial, somatoform disorders, somatization disorder, undifferentiated somatoform disorder, hypochrondriasis, conversion disorder, pain disorder, and body dysmorphic disorder.

Potential studies were also identified from bibliographies of retrieved articles, as well as several recent reviews of selected treatments (12,14,16,17). Prepost studies (i.e., where outcomes were assessed in a single group of patients before and after an intervention) were excluded. Also excluded were studies that focused on specific symptoms (e.g., back pain, headache) or functional somatic syndromes (e.g., irritable bowel syndrome, fibromyalgia).

Data were abstracted on the following key variables: somatoform disorder category, sample size, type of intervention, number of and duration of sessions, type of control group, duration of follow-up, outcomes evaluated, and treatment effect. The following types of patient-centered outcomes were evaluated: a) symptoms (i.e., the study's main measure of somatic symptom count and/or severity); b) functional status (i.e., the study's main measure of functional impairment or quality of life); and c) psychological (i.e., either a domain specific to the disorder, such as hypochondriacal or body dysmorphic beliefs and behaviors, or a generic measure of depression, anxiety, or psychological distress). For each trial, these three outcomes were assessed as positive (outcome was better in the treatment group than the control group), equivocal (there was a trend favoring the treatment group but the group difference was not statistically significant), negative (the groups did not differ), or not assessed. Secondary variables for which data were abstracted include patient demographics (age, gender, educational level, race), and country as well as type of clinic in which the study was conducted.

A standard meta-analytic approach to aggregate the reported data on efficacy was not possible because of the small number of trials for a given intervention within broad treatment classes; substantial differences in the definition and types of reported outcomes; and considerable variation in the reporting of statistical details, such as exact p values and standard deviations. Moreover, many studies neither stated what the primary outcome was nor prespecified the sample size needed to adequately test for a primary outcome. Therefore, similar to several previous literature syntheses of mental health interventions across multiple conditions (12,18), a vote-counting approach (19) was used to classify each trial as positive or negative. Any trial that reported statistically significant improvement in at least one of the three patient-centered outcomes was operationally defined as a positive trial.

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Cognitive Behaviour Therapy for Health Anxiety: A Systematic Review and Meta-Analysis

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Background: Health anxiety (HA), or hypochondriasis, is a psychological problem characterized by a preoccupation with the belief that one is physically unwell. A 2007 Cochrane review (Thomson and Page, 2007) found cognitive behavioural therapy (CBT) to be an effective intervention for individuals with HA. Similar findings were reported in a recent meta-analysis (Olatunji et al., 2014), which did not employ a systematic search strategy. The current review aimed to investigate the efficacy of CBT for HA, and to update the existing reviews. **Method:** A systematic search was conducted following Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidance, including randomized controlled trials that compared CBT with a control condition for people with HA. Five hundred and sixty-seven studies were found in the original search, of which 14 were included in the meta-analysis. **Results:** Meta-analysis was conducted on 21 comparisons and a large effect size for CBT compared with a control condition was found at post therapy $d = 1.01$ (95% confidence interval 0.77–1.25), as well as at 6- and 12-month follow-up. **Conclusions:** This systematic review and meta-analysis provides support for the hypothesis that CBT is an effective intervention for HA when compared with a variety of control conditions, e.g. treatment-as-usual, waiting list, medication, and other psychological therapies.

Key words: Hypochondriasis, health anxiety, cognitive behavioural therapy, systematic review, meta-analysis

Introduction

Hypochondriasis in DSM-IV has been redefined in DSM-5 to Illness Anxiety Disorder (American Psychiatric Association, 2013). By both definitions, this problem is characterized by preoccupation with the belief that one has, or could acquire, a serious illness, emanating from 'anxiety about the meaning, significance or cause' of their symptoms. This is accompanied by high anxiety about health and excessive health-related behaviours or maladaptive avoidance. For some time now, these problems have been referred to as 'health anxiety' (HA), and given the recent publication of DSM-5, this is the term used here.

HA is a common mental health problem; epidemiological studies report rates of 0.26–8.5% of individuals in primary care meeting DSM (Diagnostic and Statistical Manual of Mental Disorders) or ICD (International Classification of Diseases) criteria (Creed and Barsky, 2004). Gureje et al. (1997) found that individuals with abridged, or subclinical, HA had similar levels of impairment in terms of occupational role, physical impairment and health perception to those who met the full ICD-10 criteria. Warwick and Salkovskis (1990) have suggested that HA is best thought of as a continuum, with full clinical diagnosis at the upper end. Treatment

Factitious disorders 2

Factitious disorders and malingering: challenges for clinical assessment and management

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This is the second in a Series of two papers about factitious disorders

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Compared with other psychiatric disorders, diagnosis of factitious disorders is rare, with identification largely dependent on the systematic collection of relevant information, including a detailed chronology and scrutiny of the patient's medical record. Management of such disorders ideally requires a team-based approach and close involvement of the primary care doctor. As deception is a key defining component of factitious disorders, diagnosis has important implications for young children, particularly when identified in women and health-care workers. Malingering is considered to be rare in clinical practice, whereas simulation of symptoms, motivated by financial rewards, is regarded as more common in medicolegal settings. Although psychometric investigations (eg, symptom validity testing) can inform the detection of illness deception, such tests need support from converging evidence sources, including detailed interview assessments, medical notes, and relevant non-medical investigations. A key challenge in any discussion of abnormal health-care-seeking behaviour is the extent to which a person's reported symptoms are considered to be a product of choice, or psychopathology beyond volitional control, or perhaps both. Clinical skills alone are not typically sufficient for diagnosis or to detect malingering. Medical education needs to provide doctors with the conceptual, developmental, and management frameworks to understand and deal with patients whose symptoms appear to be simulated. Central to the understanding of factitious disorders and malingering are the explanatory models and beliefs used to provide meaning for both patients and doctors. Future progress in management will benefit from an increased appreciation of the contribution of non-medical factors and a greater awareness of the conceptual and clinical findings from social neuroscience, occupational health, and clinical psychology.

Introduction

Abnormal health-care-seeking behaviour covers a multitude of clinical and non-clinical behaviours ranging from symptom exaggeration to deliberate feigning.[1–4] In this Review, we focus on abnormal health-care-seeking behaviours that include simulation (factitious disorders and malingering) and propose that standard use of these terms in psychiatric classifications such as the Diagnostic and Statistical Manual of Mental Disorders (DSM)[5] has not kept abreast of conceptual and psychological advances. In line with our clinical focus, we consider non-medical explanations, in particular the neglected part that volitional and motivational factors can play. As such this Review departs from previous accounts by not explicitly endorsing the standard medical glossary definitions of factitious disorders, and questions the use and legitimacy of deception as a special form of mental disorder for several reasons.

Search strategy and selection criteria

We searched PsycINFO via Health Databases Advanced Search on the UK National Health Service evidence website from Nov 11, 2012, with the terms "FACTITIOUS DISORDERS", OR "MUNCHAUSEN SYNDROME", OR "MALINGERING". We limited our search to English-language articles published from 2000. We did a final search of PubMed on May 30, 2013, with the terms "factitious disorder" and "malingering".

First, although factitious disorders and malingering are both clinically significant, deception is a pervasive, normal, and ubiquitous social behaviour of human nature.[6] Second, abundant evidence exists to show that people (both patients and doctors) frequently engage in a range of deceptive behaviours outside medical symptom appraisal and for various reasons.[4,7,8] Third, the DSM diagnosis of a factitious disorder has little clinical validity.[9] Precisely what impairment to normal mental functioning justifies defining the intentional fabrication of illness symptoms as a mental disorder in its own right is unclear. Fourth, evidence that factitious disorders and malingering behaviours tend to be episodic, situation specific, and highly dependent on selective interactions with medical, social, or legal professionals suggests that they are not clinical states, but rather discrete "behavior governed by a cost–benefit analysis."[10] Fifth, from a clinical and diagnostic perspective, it seems unlikely that most clinicians can reliably and consistently extricate the contributory role of deception and hence distinguish factitious disorder and malingering.[11] Sixth, the diagnosis of factitious disorders (and compensation neurosis) appear to have been largely created as a way of bridging or linking diagnoses between unconsciously mediated psychiatric disorder and consciously mediated malingering.[9,12] Seventh, many existing psychiatric accounts of abnormal health-care-seeking behaviour underestimate the contribution of non-medical deception,[13] and without explicit consideration or exploration of the potential part played by volitional choice, meaningful discussion of

Section 5.0

Reports requiring discussion

HERC Use of Quality Adjusted Life Years

Question: Should the Health Evidence Review Commission (HERC) adopt a policy to limit the consideration of quality adjusted life years (QALYs) in HERC processes and decision-making?

Question source: Individuals with disabilities, disability rights advocates and pharmaceutical industry representatives

Issue: The HERC has previously used QALYs as a factor in decision-making regarding which services will be covered by the Oregon Health Plan according to the Prioritized List of Health Services. It is important for the HERC to consider the potential impact of using QALYs on health inequities.

Staff recommendation:

- Choose one of the following options (below) as draft HERC policy on use of QALYs to post for public comment for a 21-day public comment period.
- Staff will bring a revised proposal, along with all comments received, to the November 17, 2022 HERC meeting.

Options for the use of QALYs by the HERC

1. HERC staff will incorporate the following adjustments when referencing QALYs as part of their recommendation development for the HERC in order to prevent the inappropriate use of QALYs:
    a) Only use QALYs to compare treatments for the same population. QALYs will not inform scoring used to rank lines for the Prioritized List.
    b) Perform a literature search for alternative measures of cost effectiveness and cite any that are relevant.
    c) Explicitly describe the role of QALYs vis a vis other decision factors considered using a simplified Multi-Criteria Decision Analysis (defined below), including benefits, harms, costs, values and preferences and delivery system issues relevant to the topic at hand.
    d) Offer HERC's consumer advocate members an opportunity to review and comment on meeting materials prior to public meeting material release. These comments will inform potential modifications and will be shared as part of public meeting materials.
    e) Continue to explore opportunities to improve accessibility for public testimony as part of HERC deliberations.

2. Do not mention QALYs in staff-prepared meeting materials and avoid discussion of QALYs at Commission and subcommittee meetings.

3. Do not mention QALYs in staff-prepared meeting materials and do not discuss QALYs at Commission meetings. Staff will also search all studies for "QALY" and redact any mention of QALYs from published articles.

4. Do not mention QALYs in staff-prepared meeting materials and do not discuss QALYs at Commission meetings. Search all studies for "QALY" and exclude from consideration any studies reporting QALYs.

Background

What are QALYs?

QALYs are a tool used in health services research to estimate the effectiveness of a medical intervention. QALYs combine measurements of effectiveness including mortality (life years) as well as morbidity (quality of life) as part of one assessment for medical intervention effectiveness, allowing for researchers to compare changes in health status within and across conditions (Carlson et al, 2020).

Medical interventions have often been assessed based on the impact they have on mortality, which can also be defined as the extension of "life years." When calculating an impact on life years, a researcher may assess how many years of life, on average, are extended with a medical intervention compared to no intervention at all or compared to another intervention.

In the case of a QALY calculation, a life year is further adjusted for its perceived quality. The quality-of-life determination is represented as a fraction of a healthy life year and is assigned a numeric or fractional value between 0-1, where 1 would represent the highest quality of life while a 0 would represent the lowest. For example, if a healthy life year is given the value of 1, then a year of life experienced with illness or disability may be valued at less than 1 year. This quality-of-life factor can be derived through a variety of means. However, it is most often elicited through surveys that seek to determine how a health condition is perceived to affect a person's quality of life. If an intervention improves quality of life, this difference in quality of life can be factored into the evaluation. This fractional number representing the improvement resulting from the intervention is then multiplied by the total life years extended to calculate the QALY as shown here:

Improvement in quality of life (0-1) x Life years extended = Number of QALYs gained

Example: A medical intervention is shown to extend life for a population with pre-existing disability on average by 10 years. The disability is estimated to reduce quality of life by 50% each year. However, the intervention does not improve the quality of life. The QALY for this medical intervention would be: 0.5 x 10 = 5 QALYs. For a population with no disability, this calculation would be 1 (instead of 0.5) x 10 = 10 QALYs.

Some interventions improve both quality of life and life expectancy, so QALYs will show benefits for interventions which substantially improve quality of life, length of life, or both.

QALYs are also used to assess the balance between the cost of an intervention and the benefit from that intervention, also known as the cost-effectiveness. If the cost of the intervention in the example above is $100,000, then the cost per QALY ($100,000 divided by 5 QALYs) would be $20,000 for the individual with pre-existing disability, compared to $10,000 ($100,000 divided by 10 QALYs) for the for a person living without disability. In some cases, a service may be assessed to have a low-level health benefit and relatively low cost resulting in a high cost-per-QALY. Alternatively, an effective service may have a high initial cost, but a low cost-per-QALY because it provides substantial health benefit over many years.

This cost per QALY has been used to evaluate cost vs. benefit for individual medical interventions, and to compare cost effectiveness across multiple interventions. Cost-effectiveness data including cost per

QALY have been used internationally and in the US to make healthcare coverage decisions, including by the HERC on a limited basis.

Concerns raised regarding HERC's use of QALYs

The HERC's inclusion of QALYs has been an area of concern for individuals with disabilities, disability rights advocates and pharmaceutical industry representatives. The overarching concern is that the use of QALYs is discriminatory against those with disabilities and chronic illness and that QALYs devalue life with a disability.

Some specific concerns that have been raised include but are not limited to:

- QALYs may result in a higher prioritization for treatments that extend life years for healthy or younger individuals compared to those with disability, chronic disease or older age.
- The surveys used to determine impact on quality of life for the purposes of QALY calculations have validity and reliability concerns.
- QALYs may not account for subgroup differences or for individuals with rare conditions.
- Use of QALYs in determining coverage will systematically create inequities for people whose disabilities and chronic conditions can be managed but not cured.

For a detailed review of the concerns with the use of QALY, see the 2019 report from the National Council on Disability, Quality-Adjusted Life Years and the Devaluation of Life with Disability: Part of the Bioethics and Disability Series.

HERC's use of QALYs to date

Transparency is a priority for the HERC's work. In keeping with this priority, HERC staff conducted an analysis of the role of QALYs in HERC decision-making since 2017. The results appear in Appendix A.

Since 2017, all prior HERC considerations for adopting a more central role of the use of QALYs have been either rescinded, not adopted or never implemented due to concerns for their potential discriminatory effects.

In recent years, the HERC has used QALYs in a limited fashion to inform decisions about coverage based on cost-effectiveness. When HERC has considered QALY data, it has almost always resulted in expanded coverage. Further, QALYs are always used to compare treatments for the same condition, rather than different conditions. Since QALY calculations remain prominent in the medical literature, QALY data are sometimes included in the meeting materials reviewed by Commissioners, and HERC staff may reference QALYs in issue summaries to support recommendations or inform HERC considerations. This information may inform a general understanding of relative effectiveness or cost-effective of services, even when not used in the active decision-making process. Any use of QALYs in meeting materials is referenced along with other factors, including relevant information about benefits and harms, professional society recommendations, and patient values and preferences.

Alternatives to using QALYs in decision making about cost effectiveness

Cost effectiveness analysis remains a necessary component of medical decision making and, because of this, QALYs have remained in prominent use within the medical literature despite noted challenges and concerns. However, there are alternatives to QALYs when determining cost effectiveness.

HERC Use of Quality Adjusted Life Years

Listed below are alternative measures to the use of QALYs as proposed in the NCD's report about QALYs, pp. 61-68. Examples include:

- Equal Value Life Years Gained Supplemental Measure (EvLYG)
    - An unweighted measure of years of extended life without a reduction in value of a life year by the use of a disability weight. The Institute for Cost Effectiveness Research (ICER) has announced its intent to calculate this measure as a supplement to QALYs in its reviews going forward.
- Not using QALYs when determining cost effectiveness, but evaluating the cost per positive outcome
    - For instance, a drug for rheumatoid arthritis might be evaluated in terms of "cost per remission" achieved.
- Multi-Criteria Decision Analysis
    - Consider different factors relevant to a health care decision, using QALYs as one component in that decision analysis. All factors are assigned a weight according to their importance for the decision at hand; however, there are known equity challenges in the determination and application of weights in health services decision making (Wailoo, 2009; Claxton, 2015).
- Patient Perspective Value Framework
    - A five-domain healthcare decision tool that centers patient goals, patient-centered outcomes, financial costs, quality of the evidence, and usability to determine the value of the treatment. Note that this framework has never been operationalized (Jalpa, 2018).
- The Efficiency Frontier
    - A visual modeling metric that expresses treatments as points on a graph, where cost per patient is one axis (x), and benefit is another (y); cost effectiveness is determined when a treatment scores "above" a pre-determined efficiency slope.

These alternative measures are cited in the 2019 NDC report as potential substitutions for QALYs. However, these are infrequently referenced in the published medical literature. As noted above, some of these measures are hypothetical. The absence of robust alternatives to QALY metrics in the literature poses a longstanding challenge among health services researchers who acknowledge the limitations of QALYs but find few feasible alternatives (Carlson, 2020). To the extent that cost effectiveness will remain a necessary component of medical decision-making for health payers, future research to develop alternative measures or models is warranted.

References

Carlson, J. J., Brouwer, E. D., Kim, E., Wright, P., & McQueen, R. B. (2020). Alternative approaches to quality-adjusted life-year estimation within standard cost-effectiveness models: Literature review, feasibility assessment, and impact evaluation. Value in Health, 23(12), 1523-1533.

Claxton, K., Sculpher, M., Palmer, S., & Culyer, A. J. (2015). Causes for concern: is NICE failing to uphold its responsibilities to all NHS patients?. Health economics, 24(1), 1-7.

Jalpa A. Doshi, Ellen Miller Sonet, Justin T. Puckett, and Henry Glick, "The Need for a New Patient Centered Decision Tool for Value-Based Treatment Choices in Oncology," HealthAffairs (blog), Health Affairs, March 19, 2018, https://www.healthaffairs.org/do/10.1377/hblog20180309.241877/full/

National Council on Disability (NCD). (2019). Quality-adjusted life years and the devaluation of life with disability. Retrieved 9/27/22 at https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf.

Wailoo, A., Tsuchiya, A., & McCabe, C. (2009). Weighting must wait. *Pharmacoeconomics*, *27*(12), 983-989.

Appendix A: Historic use of QALY calculations in HERC decisions

All meeting materials and minutes are available on HERC's Archived Meeting Materials page.

Previous examples of HERC's use of QALYs in decision-making processes

Use Cost/QALY as a threshold for topic review or in adding new treatments

In 2017, HERC considered using a cost-per-QALY threshold for determining which services should be considered cost-effective. Discussion occurred at the March 9, 2017 and May 18, 2017 meetings. The policy had been proposed to inform research plans by the state's Pharmacy and Therapeutics Committee and the Commission regarding potential decisions to give low priority to certain non-pharmaceutical services for selected indications, or all indications. The proposed use of a cost-per-QALY threshold was abandoned due to other considerations. (March 2017 Materials Minutes, May 2017 Materials Minutes, August 2017 Materials, Minutes)

As a part of this same dialogue, the Commission discussed an algorithm (Figure 1.9, shown in Appendix A) previously developed to aid in determining which new services should be added to the Prioritized List for potential coverage or which existing services should be removed from the list based on new information.[1] The Commission voted to stop using Figure 1.9 in its biennial report and did not adopt any new rubric since each decision requires unique consideration. The meeting minutes indicate that "parts [of Figure 1.9] are unclear and other parts are incorrect."

Consideration of QALYs in end-of-life cancer care

The Health Services Commission (HERC's predecessor, which maintained the Prioritized List through 2011) added policy in October 2009 related to the treatment of cancer with little or no benefit. While this statement of intent greatly expanded coverage for advanced cancer care, it still excluded coverage for some treatments based on their predicted impact on expected median survival. It also included this language related to QALYs: "The Health Services Commission is reluctant to place a strict $/QALY (quality adjusted life-year) or $/LYS (life-year saved) requirement on end-of-life treatments, as such measurements are only approximations and cannot take into account all of the merits of an individual case. However, cost must be taken into consideration when considering treatment options near the end of life. For example, in no instance can it be justified to spend $100,000 in public resources to increase an individual's expected survival by three months when hundreds of thousands of Oregonians are without any form of health insurance." Due to staff concerns about discrimination, this policy was completely revised for the October 2014 Prioritized List, and the resulting new guideline note omitted the criteria related to QALYs, further expanding coverage for advanced cancer treatment.

Other use of QALYs on individual topics

In late 2021, staff searched meeting materials and minutes for any references to QALYs to better understand how they have been used in the Commission's decision-making. All discrete topics where

[1] In 2005, the legislature added a requirement for the HSC to consider cost effectiveness in developing the Prioritized List. In response, the HSC developed a figure which used QALYs to inform an effectiveness score which had a significant role in the ranking methodology. The role of QALYs was not determinative, but was one factor considered in the methodology. In practice, however, QALYs were only used, when available, to compare multiple treatments for the same condition.

QALYs were presented in studies provided to the Commission or referenced in discussion or issue summaries since 2017 are included in the table below. Some decisions prior to 2017 are also included in the table when relating to disability. Each decision is characterized by how the use of QALYs influenced (or may have influenced, if not discussed) a given decision.

Decisions resulting in new, expanded or reaffirmed coverage

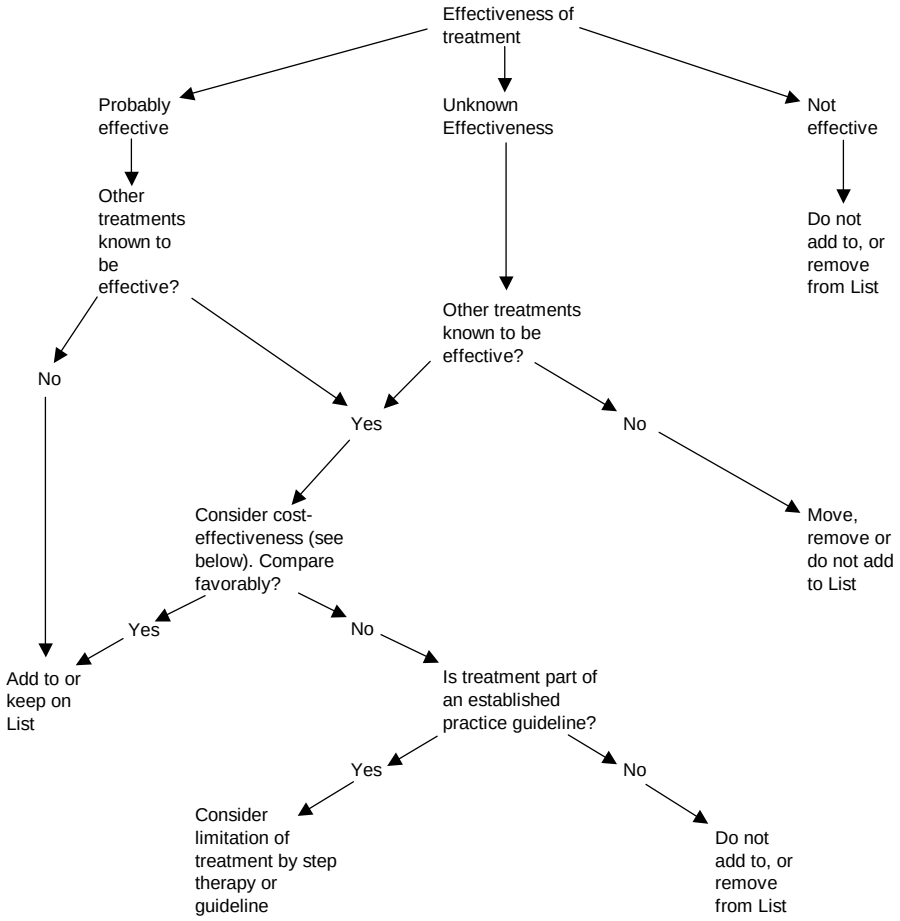
Service	Use of Cost per QALY or QALY	Meeting date(s)
Treatments for varicose veins	Minor factor supporting coverage	1/16/2020 11/14/2019 11/9/2017
Drug eluting stents	Significant impact on the decision to cover, as initial higher cost is offset by savings from fewer reoperations.	8/9/2019
Sacroiliac joint fusion	Minor factor in support of coverage	1/17/2019
Diabetes prevention program added	Significant factor supporting coverage	8/9/2018
Community health workers [race/ethnicity related]	Moderate factor supporting use of community health workers to increase cancer screening attendance	3/8/2018
Cataract coverage expansion [disability/age related]	Preventable loss in QALYs a significant factor in favor of coverage	1/18/2018
Subcutaneous cardiac rhythm monitors	Minor factor in support of coverage	11/8/2018
Deep brain stimulation for Parkinson's disease [disability/age related]	Significant factor in support of coverage	1/18/2018
Medical treatment for early stage liver fibrosis from hepatitis C	One report cited higher cost/QALY for early-stage disease. HERC made no change to coverage	2/2/2017
Cochlear implants—clarified coverage for bilateral implants [disability related]	Higher cost/QALY for second cochlear implant Cost/QALYs mentioned in 2015 report cited but not relevant to question about hearing loss threshold	3/12/2015 5/9/2013

Decisions resulting in noncoverage or restricted coverage

Service	Use of Cost per QALY, or QALY	Meeting date(s)
PET scanning for staging and restaging for breast cancer	Mentioned but not a factor in the decision (Coverage was later added in 2021, based on updated clinical practice guidelines)	3/8/2018
Digital breast tomography	High cost/QALY cited as a reason for noncoverage (due to low clinical benefit) 2/2/2017 VBBS/HERC meeting	2/2/2017

FIGURE 1.9
PROCESS FOR INCORPORATING INFORMATION ON CLINCAL INFORMATION AND COST-EFFECTIVENESS INTO THE PRIORITIZED LIST

HERC will review evidence as outlined in Figure 1.9. Evidence regarding the effectiveness of a treatment will be used according to the following algorithm:



The cost of a technology will be considered according to the grading scale below, with "A" representing compelling evidence for adoption, "B" representing strong evidence for adoption, "C" representing moderate evidence for adoption, "D" representing weak evidence for adoption and "E" being compelling evidence for rejection:

- A = more effective and cheaper than existing technology
- B = more effective and costs < $25,000/LYS or QALY > existing technology
- C = more effective and costs $25,000 to $125,000/LYS or QALY > existing technology
- D = more effective and costs > $125,000/LYS or QALY > existing technology
- E = less or equally as effective and more costly than existing technology

List of Abbreviations

- EvLYG: Equal Value Life Years Gained Supplemental Measure
- LYS: Life-year saved
- HERC: Health Evidence Review Commission
- HSC: Health Services Commission
- NDC: National Council on Disabilities
- PET: Positron emission tomography
- QALY: Quality Adjusted Life Year
- VBBS: Value-based Benefits Subcommittee

Section 6.0

Previously Discussed Items

Modifications to the Severe Inflammatory Skin Disease Guideline

Plain Language Summary:
Background: The staff of the OHA Pharmacy and Therapeutics (P&T) committee requested that language related to drug treatment be substantially modified or removed from the guideline about inflammatory skin diseases. The current language is out of date and the P&T already has guidelines regarding use of these drugs.

Should OHP change this guideline? Staff recommends HERC change the guideline to reflect current recommended utilization of these drugs.

Question: How should the severe inflammatory skin disease guideline be modified to reflect updated medication guidance?

Question source: Pharmacy and Therapeutics Committee (P&T) staff; VBBS

Issue: P&T reviewed treatments for atopic dermatitis in February 2022 and updated their prior authorization (PA) criteria for targeted immune modulators. Some of the working in current GN21 is out of date and/or does not reflect the current state of the evidence for targeted immune modulators. P&T regularly reviews these medications and new medications are coming to market on a regular basis. P&T staff are requesting that the HERC remove wording regarding these drugs to prevent internal conflicts between the Prioritized List guideline and P&T PA criteria. PA criteria can and do change at more regular intervals than Prioritized Lists can be published.

Specific issues:

1) The current guideline uses the term "biologics" when the correct term currently is "targeted immune modulators (TIMs)."
2) In the guideline, atopic dermatitis has step therapy with oral immunomodulator therapy listed as second line therapy. Based on the P&T review, oral immunomodulator therapy (i.e. targeted immune modulators) is third line therapy for this condition. From the P&T report: "Current therapies for atopic dermatitis include a variety of pharmaceutical agents and treatment modalities, including orally administered products, topical creams, and subcutaneous injections. Older therapies such as azathioprine and cyclosporine are effective, but carry the risks of significant side effects (e.g., systemic immunosuppression)." P&T requested that failure of these more high-risk medications be removed from the requirement of being failed prior to targeted immune modulators.
3) New medications are regularly being released
    a. From P&T staff: "In the past year, 3 new TIMs received FDA-approval for AD [atopic dermatitis] management. A topical JAK inhibitor, ruxolitinib (OPZELURA) was approved in September 2021. A new injectable IL-13 antagonist, tralokinumab (ADBRY), was approved in December 2021. A new oral JAK inhibitor, abrocitinib (CIBINQO) was approved in January 2022. In addition, upadacitinib (RINVOQ), an oral JAK inhibitor originally approved for rheumatoid arthritis (RA), received expanded approval for AD management in January 2022. Additional TIMs currently under investigation for AD include the oral JAK inhibitor baricitinib (OLUMIANT), currently approved for RA treatment, and 2 new injectable IL-13 antagonists, lebrikizumab and nemolizuamb. Lastly, a novel neurokinin-1 receptor antagonist, tradipitant, is being studied for AD. In all the trials for these drugs, patients were either naïve to therapy, or had failed topical

corticosteroids or calcineurin inhibitors (e.g., tacrolimus). Oral immunosuppressants were not included as step therapy."

This topic was discussed at the August, 2022 VBBS meeting. At that time, members did not agree with the staff recommendation to remove all medication references from the guideline. Staff were directed to work with P&T staff to update the medication references in the guideline. This will standardize coverage across CCO's.

After the August meeting, P&T staff made HERC staff aware that there is new P&T guidance on the treatment of vitiligo, which was recently added to a covered line. Topical calcineurin inhibitors, tacrolimus 0.03% ointment, tacrolimus 0.1% ointment, and pimecrolimus 1% cream are designated as preferred agents on the Preferred Drug List (PDL) Oral medications were not recommended for treatment of vitiligo.

Current Prioritized List guideline

GUIDELINE NOTE 21, SEVERE INFLAMMATORY SKIN DISEASE

Lines 426,482,504,533,542,656

Inflammatory skin conditions included in this guideline are:

A) Psoriasis
B) Atopic dermatitis
C) Lichen planus
D) Darier disease
E) Pityriasis rubra pilaris
F) Discoid lupus
G) Vitiligo

The conditions above are included on Line 426 if severe, defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on other validated tool) AND one or more of the following:

A) At least 10% of body surface area involved
B) Hand, foot, face, or mucous membrane involvement.

Otherwise, these conditions above are included on Lines 482, 504, 533, 542 and 656.

For severe psoriasis, first line agents include topical agents, phototherapy and methotrexate. Second line agents include other systemic agents and oral retinoids and should be limited to those who fail, or have contraindications to, or do not have access to first line agents. Biologics are included on this line only for the indication of severe plaque psoriasis; after documented failure of first line agents and failure of (or contraindications to) a second line agent.

For severe atopic dermatitis/eczema, first-line agents include topical moderate- to high- potency corticosteroids and narrowband UVB. Second line agents include topical calcineurin inhibitors (e.g. pimecrolimus, tacrolimus), topical phosphodiesterase (PDE)-4 inhibitors (e.g. crisaborole), and oral immunomodulatory therapy (e.g. cyclosporine, methotrexate, azathioprine, mycophenolate mofetil, or oral corticosteroids). Use of the topical second line agents (e.g. calcineurin inhibitors and

phosphodiesterase (PDE)-4 inhibitors) should be limited to those who fail or have contraindications to first line agents. Biologic agents are included on this line for atopic dermatitis only after failure of or contraindications to at least one agent from each of the following three classes: 1) moderate to high potency topical corticosteroids, 2) topical calcineurin inhibitors or topical phosphodiesterase (PDE)-4 inhibitors, and 3) oral immunomodulator therapy.

ICD-10-CM Q82.8 (Other specified congenital malformations of skin) is included on Line 426 only for Darier disease.

Evidence

1) **DERP 2022** report on treatments for severe atopic dermatitis
    a. N=40 studies
    b. Efficacy:
        i. Abrocitinib was more efficacious than placebo (high strength of evidence)
        ii. Azathioprine was more efficacious than placebo (low strength of evidence) and had higher adverse events
        iii. Cyclosporine was more efficacious than placebo (very low strength of evidence, with much higher rates of adverse events
        iv. Omalizumab was more efficacious than placebo (low strength of evidence) with similar adverse events
            1. Note: not FDA approved for atopic dermatitis
        v. Ruxolutinib was more efficacious than placebo (high strength of evidence)
            1. Note: only FDA approved for mild to moderate atopic dermatitis
        vi. Tralokinumab was more efficacious than placebo, although results with inconsistent (low to moderate strength of evidence)
        vii. Upadacitinib was more efficacious than placebo (high strength of evidence) with some serious adverse events

Expert guidelines

1) **American Academy of Dermatology 2020** psoriasis guidelines https://www.jaad.org/article/S0190-9622(22)00080-9/fulltext#secsectitle0170
    a. Topical steroids and vitamin D analogs are only recommended for mild to moderate disease
        i. If not effective after a 4-week trial, systemic biologic, non-biologic systemic or phototherapy is recommended
        ii. Coal tar, anthralin, tazarotene and topical salicylic acid are other options that can be considered
    b. Phototherapy is recommended for generalized psoriasis and guttate psoriasis and may be used with a topical or systemic therapy
        i. Targeted phototherapy can be used for localized disease with or without systemic or combination therapy
    c. Systemic non-biologics (Acitretin, apremilast, cyclosporine, fumaric acid esters, methotrexate, tofacitinib, and other immunosuppressants
        i. Recommended for patients with BSA>10% or involving special area
        ii. If not effective or not recommended for continuous use, consider changing to topic, biologics, phototherapy or combination therapy

   d. Biologic therapy (TNF-alpha inhibitor, IL-12/23 inhibitor, IL-17 inhibitor, IL-23 inhibitor
      i. Moderate to severe psoriasis or disease involving special areas
2) **American Academy of Dermatology 2014** guidelines on management of atopic dermatitis with topical therapies
   a. Topical calcineurin inhibitors have an A recommendation with a level I strength of evidence
      i. TCI are recommended and effective for acute and chronic treatment, along with maintenance, in both adults and children with AD, and are particularly useful in selected clinical situations
         1. When topical steroids are not effective
         2. Sensitive areas (face, anogenital, etc.)
         3. When steroid induced atrophy is present
         4. When the patient requires long term uninterrupted topical steroid use
   b. Topical corticosteroids have an A recommendation with a level I strength of evidence
      i. TCS are used in the management of AD in both adults and children and are the mainstay of anti-inflammatory therapy
3) **American Academy of Dermatology 2014** guidelines on management of atopic dermatitis with phototherapy and systemic agents
   a. Phototherapy is a second-line treatment, after failure of first-line treatment (emollients, topical steroids, and topical calcineurin inhibitors).
   b. [systemic agents] are indicated and recommended in AD care for the subset of adult and pediatric patients in whom optimized topical regimens and/or phototherapy do not adequately control the disease, or when QOL is substantially impacted

<u>Expert input</u>:

Dr. Julie Dhossche, OHSU pediatric dermatology

There's really little data on "1st" and "2nd" line treatments for "severe" eczema and a lot comes down to a judgment call and shared decision making.

I personally encounter a lot of pediatric-specific issues with the guideline so I like your suggestion of and/or for phototherapy. a lot of the kids I treat are too young to stand in a photobooth alone, plus it often presents significant disruption in school and/or work to come to the office 2-3 times a week for months at a time. The other thing I would suggest changing is mycophenolate and azathioprine (THERE IS NO DATA FOR PEDS and very poor data for adults)-- this is not a reasonable request to require this before dupilumab, the FDA approved medication down to 6 months of age. There is no pediatric dermatologist who would put a 3 year old on azathioprine for atopic dermatitis. **In fact I heavily advocate removing mycophenolate and azathioprine completely from the guideline. And I would argue oral corticosteroids need to go as well--no longer a widely accepted treatment for AD.** we'll also need to add upadicitinib, the oral jak inhibitor approved for those 12 and older for atopic dermatitis--currently not on the guideline.

For psoriasis, I agree, any biologics would be appreciated first-line for severe psoriasis (this is the current practice for dermatology) and using the cheapest ones are ok and better than traditional systemics like MTX or acitretin. There are like 13 to choose from so it seems like you could search for the best price with little competition.

I'm circling back after some additional discussions with local experts as well as colleagues nationally. I'll tell you that it seems like in quite a number of states, dupilumab is now a first-line treatment for severe eczema from their Medicaid, given its FDA approval and superior efficacy.

The other thing we wanted to point out is that phototherapy is not always an appropriate treatment for those with severe atopic dermatitis, as in some instances, it can worsen severe inflammation due to burning/heat, so we'd prefer this not be considered on the same level as an immunomodulator drug--e.g. I would never use phototherapy in someone who has flaring AD >90% of their BSA as it is high risk to acutely worsen and takes at least 3-4 months to help if it does help.

Modifications to the Severe Inflammatory Skin Disease Guideline

HERC staff summary

For psoriasis, TIMs and other systemic therapy are now first line for severe disease (>10% BSA or special areas). Topical agents are only used in specific circumstances, mainly with less severe disease.

For atopic dermatitis, current therapies include a variety of pharmaceutical agents and treatment modalities, including orally administered products, topical creams, and subcutaneous injections. Older therapies such as azathioprine and cyclosporine are effective, but carry the risks of significant side effects (e.g., systemic immunosuppression). In all the trials for oral targeted immune modulator drugs, patients were either naïve to therapy, or had failed topical corticosteroids or calcineurin inhibitors (e.g., tacrolimus). Oral immunosuppressants were not included as step therapy.

HERC staff recommendation:

1) Option 1: delete all language related to medications in GN21 (delete the two edited paragraphs below)
2) Option 2: Modify GN 21 as shown below
    a. Alternatively, the paragraphs regarding drug therapy could simply be deleted as the current version has very little information on any step therapy
    b. The guideline is first shown with changes indicated; then shown without marked changes for easier review

GUIDELINE NOTE 21, SEVERE INFLAMMATORY SKIN DISEASE

Lines 426,482,504,533,542,656

Inflammatory skin conditions included in this guideline are:

A) Psoriasis
B) Atopic dermatitis
C) Lichen planus
D) Darier disease
E) Pityriasis rubra pilaris
F) Discoid lupus
G) Vitiligo

The conditions above are included on Line 426 if severe, defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on other validated tool) AND one or more of the following:

C) At least 10% of body surface area involved
D) Hand, foot, face, or mucous membrane involvement.

Otherwise, these conditions above are included on Lines 482, 504, 533, 542 and 656.

For severe psoriasis, treatments included on this line are topical agents, phototherapy, targeted immune modulator medications and other systemic medications. ~~first line agents include topical agents, phototherapy and methotrexate. Second line agents include other systemic agents and oral retinoids and should be limited to those who fail, or have contraindications to, or do not have access to first line agents. Biologics are included on this line only for the indication of severe plaque psoriasis; after documented failure of first line agents and failure of (or contraindications to) a second line agent.~~

Modifications to the Severe Inflammatory Skin Disease Guideline

For severe atopic dermatitis/eczema, ~~first-line agents include~~ treatments included on this line are topical moderate- to high- potency corticosteroids, topical calcineurin inhibitors (~~e.g.~~ for example, pimecrolimus, tacrolimus), narrowband UVB~~. Second line agents include topical calcineurin inhibitors (e.g. pimecrolimus, tacrolimus),~~ topical phosphodiesterase (PDE)-4 inhibitors ~~(e.g. crisaborole)~~, and oral immunomodulatory therapy (e.g. cyclosporine, methotrexate, ~~azathioprine, mycophenolate mofetil,~~ or oral corticosteroids). ~~Use of the topical second line agents (e.g. calcineurin inhibitors and phosphodiesterase (PDE)-4 inhibitors) should be limited to those who fail or have contraindications to first line agents. Biologic agents~~ Targeted immune modulators (for example, dupilumab) are included on this line ~~for atopic dermatitis only after failure of or contraindications to at least one agent from each of the following three classes: 1) moderate to high potency topical corticosteroids, 2) topical calcineurin inhibitors or topical phosphodiesterase (PDE)-4 inhibitors, and 3) oral immunomodulator therapy.~~ when

1) prescribed in consultation with a dermatologist or allergist or immunologist
AND
2) The patient has failed (defined as inadequate efficacy, intolerable side effects, or side effects that pose a health risk) either a
    a. 4 week trial of a combination of topical moderate to high potency topical steroids and a topical non-steroidal agent, OR an oral immunomodulator OR
    b. 12 weeks of phototherapy.

JAK inhibitor (upadacitinib) therapy is included on this line when other immunomodulatory therapy has failed to adequately control disease (defined as inadequate efficacy, intolerable side effects, or side effects that pose a health risk).

ICD-10-CM Q82.8 (Other specified congenital malformations of skin) is included on Line 426 only for Darier disease.

Modified guideline without changes shown

GUIDELINE NOTE 21, SEVERE INFLAMMATORY SKIN DISEASE

Lines 426,482,504,533,542,656

Inflammatory skin conditions included in this guideline are:

H) Psoriasis
I) Atopic dermatitis
J) Lichen planus
K) Darier disease
L) Pityriasis rubra pilaris
M) Discoid lupus
N) Vitiligo

The conditions above are included on Line 426 if severe, defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on other validated tool) AND one or more of the following:

E) At least 10% of body surface area involved
F) Hand, foot, face, or mucous membrane involvement.

Otherwise, these conditions above are included on Lines 482, 504, 533, 542 and 656.

Modifications to the Severe Inflammatory Skin Disease Guideline

For severe psoriasis, treatments included on this line are topical agents, phototherapy, targeted immune modulator medications and other systemic medications.

For severe atopic dermatitis/eczema, treatments included on this line are topical moderate- to high-potency corticosteroids, topical calcineurin inhibitors (e.g. pimecrolimus, tacrolimus), narrowband UVB, topical phosphodiesterase (PDE)-4 inhibitors, and oral immunomodulatory therapy (for example, cyclosporine, methotrexate, or oral corticosteroids). Targeted immune modulators (for example, dupilumab) are included on this line when

1) prescribed in consultation with a dermatologist or allergist/immunologist
AND
2) The patient has failed (defined as inadequate efficacy, intolerable side effects, or side effects that pose a health risk) either a
    a. 4 week trial of a combination of topical moderate to high potency topical steroids and a topical non-steroidal agent, OR an oral immunomodulator OR
    b. 12 weeks of phototherapy.

JAK inhibitor (upadacitinib) therapy is included on this line when other immunomodulatory therapy has failed to adequately control disease (defined as inadequate efficacy, intolerable side effects, or side effects that pose a health risk).

ICD-10-CM Q82.8 (Other specified congenital malformations of skin) is included on Line 426 only for Darier disease.

Drug Use Research & Management Program
Oregon State University, 500 Summer Street NE, E35
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Drug Class Literature Scan: Medications for Vitiligo

Date of Review: June 2022

Date of Last Review: N/A
Literature Search: 1946 - 03/21/2022

Current Status of PDL Class:
See **Appendix 1**.

Conclusions:

- The objective of a 2015 Cochrane review was to update a 2010 review that assessed the effects of therapeutic interventions used in the management of vitiligo.[1] This review identified evidence from individual studies to support existing therapies for vitiligo, but the usefulness of the findings is limited by the different designs, outcome measurements and lack of quality of life measures.[1] There is moderate evidence for the use of topical corticosteroids (TCS), although long-term use is likely to lead to adverse effects.[1] When used as monotherapy, it may be preferable to use super potent TCS preparations to give a better chance of therapeutic response, but close monitoring for adverse effects is necessary.[1] The topical calcineurin inhibitor (TCI), tacrolimus, seems to be a reasonable alternative to topical corticosteroids, particularly on anatomical sites where there may be a higher risk of adverse effects with TCS.[1]
- In 2021, the British Association of Dermatologists (BAD) updated a 2008 guideline for the management of vitiligo for implementation in the United Kingdom National Health Service.[2] First-line treatments consist of topical treatments TCS and TCI.[2] Commonly prescribed TCS include betamethasone dipropionate, clobetasol dipropionate and fluticasone.[2] Tacrolimus, as monotherapy or in combination with phototherapy, is just as effective as TCS therapy but has a safer side-effect profile.[2] Second-line treatments consist of phototherapy (narrow band ultra violet B rays [NB-UVB] or psoralen and UVA [PUVA]) and systemic steroid treatment.[2] Third-line treatments consist of surgical grafting techniques.[2] Despite the autoimmune nature of vitiligo, there is insufficient evidence to support the use of immunosuppressive therapies in managing vitiligo.[2]
- In January 2022, the Oregon HERC revised Guideline Note 21 to broaden coverage of severe inflammatory skin disease.[3] Inflammatory skin conditions in this guideline include: psoriasis, atopic dermatitis, lichen planus, darier disease, pityriasis ruba pilaris, discoid lupus, and vitiligo. Severe forms of these conditions are funded on line 426 and are defined as having functional impairment AND one or more of the following:
    A) At least 10% of body surface area (BSA) involved
    B) Hand, foot, face, or mucous membrane involvement

Recommendations:

- Revise prior authorization (PA) criteria for “Topical Agents for Inflammatory Skin Diseases” to reflect most recent Oregon Health Effectiveness Review Committee (HERC) guidance described in Guideline Note 21.
- After review of costs of topical steroids in Executive Session, betamethasone-propylene glycol cream, clobetasol propionate solution, desoximetasone cream, and hydrocortisone cream products were changed to preferred.

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Summary of Current Policy

- In January 2022, the Oregon HERC revised Guideline Note 21 to broaden coverage of severe inflammatory skin disease.[3] Inflammatory skin conditions in this guideline include: psoriasis, atopic dermatitis, lichen planus, darier disease, pityriasis ruba pilaris, discoid lupus, and vitiligo. Severe forms of these conditions are funded on line 426 and are defined as having functional impairment AND one or more of the following:
    - At least 10% of body surface area (BSA) involved
    - Hand, foot, face, or mucous membrane involvement

  The definition of functional impairment, is defined as an assessment of severe disease using the Dermatology Life Quality Index (DLQI) (score $\geq$ 11), Children's Dermatology Life Quality Index (CDLQI) (score $\geq$ 13), or severe score on another validated tool.[3] If inflammatory skin conditions do not meet the criteria stipulated in Guideline Note 21, they are not funded by HERC and are included on lines 482, 504, 532, 541, and 656. The revised 2022 Guideline Note 21 is included in **Appendix 4.**
- Topical calcineurin inhibitors, tacrolimus 0.03% ointment, tacrolimus 0.1% ointment, and pimecrolimus 1% cream are designated as preferred agents on the Preferred Drug List (PDL). The Pharmacy and Therapeutics Committee reviewed topical steroids at the July 2017 meeting. No new comparative evidence was identified since the last review to support a difference in safety or efficacy among equipotent topical corticosteroids. At least one agent in each of the potency categories is designated as preferred on the PDL. A list of preferred topical agents for inflammatory skin conditions is included in **Appendix 1**.

Background:

Vitiligo, a chronic autoimmune skin disorder disease, is the most frequent cause of depigmentation worldwide, with an estimated prevalence of 1%.[4] It usually begins after birth and, although it can develop in childhood, the average age of onset is about 20 years.[5] This disorder can be psychologically devastating and stigmatizing, especially in dark skinned individuals.[4] Vitiligo is clinically characterised by the development of white macules due to the loss of functioning melanocytes in the skin or hair, or both.[4] Two forms of the disease are recognized: segmental vitiligo (SV) and non-segmental vitiligo (NSV).[6] Non-segmental vitiligo, the most common form of vitiligo, is characterized by symmetrical and bilateral white patches.[4] Non-segmental vitiligo develops at all ages, but usually occurs in young people between the ages of 10 years and 30 years.[4] The most commonly affected sites are the fingers, wrists, axillae, groin, mouth, eyes and genitalia.[7] Different NSV clinical subtypes have been described, including generalized, mucosal, acrofacial, and universal, all with a bilateral distribution.[4] In contrast, SV is less common than NSV and usually has asymmetrical, one-sided or band-shaped distribution.[4] Segmental vitiligo accounts for 5–16% of overall vitiligo cases.[4] Segmental vitiligo tends to occur at a young age, before age 30 years in 87% of cases and before age 10 years in 41% of cases.[4]

Vitiligo is classified as an autoimmune disease.[8] Recent evidence points towards an overlapping inflammatory pathogenesis for both SV and NSV.[8] Both types seem to involve a multistep process, which involves initial release of proinflammatory cytokines and neuropeptides elicited by external or internal injury, with subsequent vascular dilatation and immune response.[8] Many studies support the association of vitiligo with thyroid disorders and other associated autoimmune diseases, such as rheumatoid arthritis, psoriasis, adult-onset diabetes mellitus, Addison's disease, pernicious anemia, alopecia areata, and systemic lupus erythematosus.[4] Almost one-third of people with vitiligo have a positive family history of the disease.[4] Several corresponding relevant genes associated with both vitiligo and other pigmentary, autoimmune and autoinflammatory disorders have now been identified.[8] They are involved in immune regulation, melanogenesis and apoptosis.[8]

The diagnosis of vitiligo is generally straightforward, made clinically based upon the finding of acquired, amelanotic, nonscaly, chalky-white macules with distinct margins in a typical distribution: periorificial, lips and tips of distal extremities, penis, segmental and areas of friction.[8] The diagnosis of vitiligo does not usually

require confirmatory laboratory tests.[8] A skin biopsy or other tests are not necessary except to exclude other disorders.[8] The diagnosis of vitiligo may be facilitated by the use of a Wood's lamp, a hand-held ultraviolet (UV) irradiation device that emits ultraviolet A rays (UVA).[8] It helps identify focal melanocyte loss and detect areas of depigmentation that may not be visible to the naked eye, particularly in pale skin.[8] Under the Wood's light, the vitiligo lesions emit a bright blue-white fluorescence and appear sharply demarcated.[8]

Treatment of vitiligo aims to halt disease spread and facilitate repigmentation.[9] Choice of treatment depends on several factors including: the subtype of the disease, the extent, distribution and activity of disease as well as the patient's age, phototype, effect on quality of life and motivation for treatment.[8] The face, neck, trunk and mid-extremities respond best to therapy, while the lips and distal extremities are more resistant.[8] The 2021 BAD Guidelines recommend that first-line treatment consist of high potency or very high potency TCS or topical tacrolimus.[2] Commonly prescribed TCS include betamethasone dipropionate, betamethasone valerate, clobetasol dipropionate and fluticasone propionate.[2] Use of the TCS or tacrolimus ointment, to treat vitiligo is off-label.[10] Topical tacrolimus, as monotherapy or in combination with phototherapy, is just as effective as TCS therapy but has a safer side-effect profile.[2] Second-line treatments consist of phototherapy NB-UVB or psoralen PUVA and systemic steroid treatment.[2] Third-line treatment consists of surgical grafting techniques.[2] Despite the autoimmune nature of vitiligo, there is insufficient evidence to support the use of immunosuppressive therapies in managing vitiligo.[2] Phototherapy has been a mainstay of treatment for vitiligo for several years.[5] Phototherapy is typically administered three times per week and is more effective if commenced early on in the disease.[11] It is used as first-line therapy in extensive disease. It can be used in combination with TCS or topical tacrolimus.[2]

Methods:
A Medline literature search for new systematic reviews and randomized controlled trials (RCTs) assessing clinically relevant outcomes to active controls, or placebo if needed, was conducted. A summary of the clinical trials is available in **Appendix 2** with abstracts presented in **Appendix 3**. The Medline search strategy used for this literature scan is available in **Appendix 4**, which includes dates, search terms and limits used. The OHSU Drug Effectiveness Review Project, Agency for Healthcare Research and Quality (AHRQ), National Institute for Health and Clinical Excellence (NICE), Department of Veterans Affairs, and the Canadian Agency for Drugs and Technologies in Health (CADTH) resources were manually searched for high quality and relevant systematic reviews. When necessary, systematic reviews are critically appraised for quality using the AMSTAR tool and clinical practice guidelines using the AGREE tool. The FDA website was searched for new drug approvals, indications, and pertinent safety alerts.

The primary focus of the evidence is on high quality systematic reviews and evidence-based guidelines. Randomized controlled trials will be emphasized if evidence is lacking or insufficient from those preferred sources.

New Systematic Reviews:
2015 Cochrane: Interventions for Vitiligo
The objective of a 2015 Cochrane review was to update a 2010 review that assessed the effects of therapeutic interventions used in the management of vitiligo.[1] The literature search was conducted through October 2013.[1] The 2015 update identified 39 new randomized controlled trials (RCTs) which added to the 57 RCTs in the previous review makes a total of 96 studies, totaling 4512 participants.[1] Most of the studies (72%) were small and had fewer than 50 participants.[1] Narrowband UVB light was used in 35 RCTs, either alone or in combination with other therapies.[1] Eighteen studies evaluated surgical management and 31 studies compared active treatment versus placebo.[1] Half of the studies lasted longer than six months.[1] Only 7 studies assessed children.[1] Most of the studies included subjects with NSV, only 1 RCT included participants with SV.[1] Most of the studies were conducted in Asia or Australia (n=49) followed by Europe (n=27), the Americas (n=14), and Africa (n=6).[1] Only 5 studies met the criteria for a well-designed trial.[1] Poor design, the number and complexity of the treatments and the fact that many of the studies assessed individual vitiligo patches in the same participant, made comparison of the studies difficult.[1]

Primary outcomes included: quality of life using a validated tool (e.g. DLQI), percentage of repigmentation (success rate defined as 75% or greater repigmentation), and adverse effects.[1] Nine studies assessed quality of life and showed no significant improvement between comparators.[1] Approximately half of the studies assessed repigmentation.[1] Only 3 RCTs reported a statistically significant result for 75% or greater repigmentation with the following results: topical corticosteroids were better than PUVA-sol (psoralen with sunlight) (RR 4.70, 95% CI 1.14 to 19.39, one study, N = 45); hydrocortisone plus laser light was better than laser light alone (RR 2.57, 95% CI 1.20 to 5.50, one study, N = 84); and oral minipulse of prednisolone (OMP) plus NB-UVB was better than OMP alone (RR 7.41, 95% CI 1.03 to 53.26, one study, N = 47).[1] None of the studies reported the long-term benefit of the treatment (i.e. two years sustained repigmentation).[1] The maximum follow-up time, reported in only one study, was one year post-treatment.[1]

Studies assessing topical preparations, in particular TCS, reported the most adverse effects.[1] Most studies examining TCS reported adverse effects including folliculitis, burning, mild pruritus, dryness, mild erythema, atrophy, telangiectasia and acneiform lesions.[1] In studies combining phototherapy and TCS, it was difficult to ascertain which treatment caused these effects.[1] In a meta-analysis comparing NB-UVB to PUVA, the NB-UVB group reported less observations of nausea in three studies (RR 0.13, 95% CI 0.02 to 0.69; I^2 = 0% three studies, N = 156) and erythema in two studies (RR 0.73, 95% CI 0.55 to 0.98; I^2 = 0%, two studies, N = 106), but no itching in two studies (RR 0.57, 95% CI 0.20 to 1.60; I^2 = 0%, two studies, N = 106).[1]

This review identified evidence from individual studies to support existing therapies for vitiligo, but the usefulness of the findings is limited by the different study designs, outcome measurements, and lack of quality of life measures.[1] There is moderate evidence for the use of TCS, although long-term use is likely to lead to adverse effects.[1] When used as monotherapy, it may be preferable to use super potent TCS preparations to provide optimal therapeutic response, but close monitoring for adverse effects is necessary.[1] The TCI, tacrolimus ointment, seems to be a reasonable alternative to TCS, particularly on anatomical sites where there may be a higher risk of adverse effects with TCS.[1] There is a need for follow-up studies to assess permanence of repigmentation as well as high-quality randomized trials using standardized measures and which also address quality of life.[1]

After review, 5 systematic reviews were excluded due to poor quality, wrong study design of included trials (e.g., observational), comparator (e.g., no control or placebo-controlled), or outcome studied (e.g., non-clinical).[12-16]

New Guidelines:

British Association of Dermatologists

In 2021, BAD updated a 2008 guideline for the management of vitiligo for implementation in the United Kingdom National Health Service.[2] The National Institute for Health and Care Excellence (NICE) accredited the process used by BAD to produce the clinical guidelines.[2] A literature search was conducted through May 2019 to identify key articles on vitiligo.[2] Nearly all the evidence supporting BAD recommendations relate to studies in adults.[2] There is very little published evidence for treatment interventions in children aged under 12 years.[2] Young children are more at risk from skin atrophy from TCS treatment, especially on delicate areas such as the face.[2] Nonsteroid options such as tacrolimus should be considered first line alongside potent TCS in children.[2] Topical potent and very potent steroids are more likely to have a systemic effect due to the increased surface-area-to-volume ratio in young children, and caution should be exercised regarding their use, especially in generalized widespread disease.[2]

Treatment recommendations for adults with vitiligo are as follows:

Topical Therapies

- Offer a potent or very potent TCS once daily, to minimize potential side-effects, to people with vitiligo as the first-line treatment, avoiding the periocular area. (Strong Recommendation)[2]

- Consider topical tacrolimus 0.1% ointment twice daily in people with facial vitiligo as an alternative to potent or very potent topical corticosteroids. (Weak Recommendation)[2]
- Consider topical tacrolimus 0.1% ointment twice daily under occlusion on photoexposed areas only in people with nonfacial vitiligo as an alternative to potent or very potent TCS. (Weak Recommendation)[2]
- There is insufficient evidence to recommend topical vitamin D analogs (i.e. calcipotriene) in people with vitiligo.[2]

Systemic Therapies

- Consider oral betamethasone 0.1 mg/kg twice weekly on two consecutive days for 3 months followed by tapering of the dose by 1 mg per month for a further 3 months in combination with NB-UVB in people with rapidly progressive vitiligo to arrest activity of the disease, after careful consideration of the risks and benefits. (Weak Recommendation)[2]
- Do not offer azathioprine in combination with PUVA (or NB-UVB) to people with vitiligo, due to the risk of malignancy. (Strong Recommendation)[2]
- There is insufficient evidence to recommend any currently available systemic treatments as monotherapy for people with stable vitiligo.[2]
- There is insufficient evidence to recommend minocycline, methotrexate or tofacitinib for people with vitiligo.[2]

Light and Laser Therapy

- Offer NB-UVB (whole body or localized, e.g. home based handheld) as first-line phototherapy to people with vitiligo who have an inadequate response to topical therapy and/or who have extensive or progressive disease. (Strong Recommendation)[2]
- Consider excimer laser or light in people with localized vitiligo in combination with TCIs (more evidence for tacrolimus). (Weak Recommendation)[2]
- There is insufficient evidence to recommend combination treatment of potent or very potent TCS with NB-UVB plus CO_2 laser for people with vitiligo.[2]

A patient management algorithm was developed to be used in conjunction with the summary of recommendations and supporting information provided in the BAD publication.[2]

First line treatment:

- Offer a potent or very potent TCS once daily.[2]
- Consider topical tacrolimus 0.1% ointment twice daily in people with facial vitiligo especially the periocular region.[2]
- Consider topical tacrolimus 0.1% ointment twice daily under occlusion on photoexposed areas only in people with nonfacial vitiligo.[2]
- Consider an intermittent regimen, e.g. alternating weeks of once-daily application of potent or very potent TCS with or without topical tacrolimus for areas with thinner skin.[2]

Second line treatment:

- Offer NB-UVB (whole-body or localized) with or without TCS or topical calcineurin inhibitors.[2]
- For rapidly progressing disease, consider oral betamethasone 0.1 mg/kg twice weekly on two consecutive days for 3 months followed by tapering of the dose by 1 mg per month for a further 3 months in combination with NB-UVB.[2]

Third line treatment:

- Consider excimer laser/light with TCIs for localized vitiligo.[2]
- Consider cellular grafting for stable segmental or nonsegmental vitiligo.[2]

After review, 3 guidelines were excluded due to poor quality.[17-19]

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Appendix 1: Current Preferred Drug List

Topical Products for Atopic Dermatitis

Generic	Brand	Route	Form	PDL
pimecrolimus	ELIDEL	TOPICAL	CREAM (G)	Y
pimecrolimus	PIMECROLIMUS	TOPICAL	CREAM (G)	Y
tacrolimus	PROTOPIC	TOPICAL	OINT. (G)	Y
tacrolimus	TACROLIMUS	TOPICAL	OINT. (G)	Y
crisaborole	EUCRISA	TOPICAL	OINT. (G)	N
ruxolitinib phosphate	OPZELURA	TOPICAL	CREAM (G)	N

Topical Steroids

Generic	Brand	Route	Form	PDL
alclometasone dipropionate	ALCLOMETASONE DIPROPIONATE	TOPICAL	CREAM (G)	Y
alclometasone dipropionate	ALCLOMETASONE DIPROPIONATE	TOPICAL	OINT. (G)	Y
betamethasone dipropionate	BETAMETHASONE DIPROPIONATE	TOPICAL	CREAM (G)	Y
betamethasone dipropionate	ALPHATREX	TOPICAL	LOTION	Y
betamethasone dipropionate	BETAMETHASONE DIPROPIONATE	TOPICAL	LOTION	Y
betamethasone dipropionate	ALPHATREX	TOPICAL	OINT. (G)	Y
betamethasone dipropionate	BETAMETHASONE DIPROPIONATE	TOPICAL	OINT. (G)	Y
betamethasone valerate	BETAMETHASONE VALERATE	TOPICAL	CREAM (G)	Y
betamethasone valerate	BETATREX	TOPICAL	CREAM (G)	Y
betamethasone valerate	BETAMETHASONE VALERATE	TOPICAL	OINT. (G)	Y
betamethasone valerate	BETATREX	TOPICAL	OINT. (G)	Y
clobetasol propionate	CLOBETASOL PROPIONATE	TOPICAL	CREAM (G)	Y
clobetasol propionate	CLOBETASOL PROPIONATE	TOPICAL	OINT. (G)	Y
desonide	DESONIDE	TOPICAL	CREAM (G)	Y
desonide	DESOWEN	TOPICAL	CREAM (G)	Y
desonide	TRIDESILON	TOPICAL	CREAM (G)	Y
desonide	DESONIDE	TOPICAL	OINT. (G)	Y
desonide	TRIDESILON	TOPICAL	OINT. (G)	Y
fluocinolone acetonide	FLUOCINOLONE ACETONIDE	TOPICAL	CREAM (G)	Y
fluocinolone acetonide	SYNALAR	TOPICAL	CREAM (G)	Y
fluocinolone acetonide	FLUOCINOLONE ACETONIDE	TOPICAL	SOLUTION	Y
fluocinolone acetonide	SYNALAR	TOPICAL	SOLUTION	Y
fluocinonide	FLUOCINONIDE	TOPICAL	CREAM (G)	Y

fluocinonide	VANOS	TOPICAL	CREAM (G)	Y
fluocinonide	FLUOCINONIDE	TOPICAL	SOLUTION	Y
fluocinonide/emollient base	FLUOCINONIDE-E	TOPICAL	CREAM (G)	Y
hydrocortisone	ANTI-ITCH	TOPICAL	CREAM (G)	Y
hydrocortisone	HYDROCORTISONE	TOPICAL	CREAM (G)	Y
hydrocortisone	HYDROCORTISONE	TOPICAL	CREAM (G)	Y
hydrocortisone	HYCORT	TOPICAL	OINT. (G)	Y
hydrocortisone	HYDROCORTISONE	TOPICAL	OINT. (G)	Y
hydrocortisone	HYDROCORTISONE	TOPICAL	OINT. (G)	Y
hydrocortisone acetate	HYDROCORTISONE ACETATE	TOPICAL	CREAM (G)	Y
hydrocortisone butyrate	HYDROCORTISONE BUTYRATE	TOPICAL	SOLUTION	Y
triamcinolone acetonide	TRIAMCINOLONE ACETONIDE	TOPICAL	CREAM (G)	Y
triamcinolone acetonide	TRIAMCINOLONE ACETONIDE	TOPICAL	OINT. (G)	Y
triamcinolone acetonide	TRIANEX	TOPICAL	OINT. (G)	Y
amcinonide	AMCINONIDE	TOPICAL	CREAM (G)	N
betamethasone dipropionate	DIPROSONE	TOPICAL	AEROSOL	N
betamethasone dipropionate	BETAMETHASONE DIPROP AUGMENTED	TOPICAL	GEL (GRAM)	N
betamethasone valerate	BETAMETHASONE VALERATE	TOPICAL	FOAM	N
betamethasone valerate	LUXIQ	TOPICAL	FOAM	N
betamethasone valerate	BETAMETHASONE VALERATE	TOPICAL	LOTION	N
betamethasone/propylene glyc	BETAMETHASONE DIPROP AUGMENTED	TOPICAL	CREAM (G)	N
betamethasone/propylene glyc	BETAMETHASONE DIPROP AUGMENTED	TOPICAL	LOTION	N
betamethasone/propylene glyc	BETAMETHASONE DIPROP AUGMENTED	TOPICAL	OINT. (G)	N
betamethasone/propylene glyc	DIPROLENE	TOPICAL	OINT. (G)	N
clobetasol propionate	CLOBETASOL PROPIONATE	TOPICAL	FOAM	N
clobetasol propionate	OLUX	TOPICAL	FOAM	N
clobetasol propionate	CLOBETASOL PROPIONATE	TOPICAL	GEL (GRAM)	N
clobetasol propionate	IMPEKLO	TOPICAL	LOT MD PMP	N
clobetasol propionate	CLOBETASOL PROPIONATE	TOPICAL	LOTION	N
clobetasol propionate	CLOBETASOL PROPIONATE	TOPICAL	SHAMPOO	N
clobetasol propionate	CLOBEX	TOPICAL	SHAMPOO	N
clobetasol propionate	CLODAN	TOPICAL	SHAMPOO	N
clobetasol propionate	CLOBETASOL PROPIONATE	TOPICAL	SOLUTION	N
clobetasol propionate	CLOBETASOL PROPIONATE	TOPICAL	SPRAY	N
clobetasol propionate	CLOBEX	TOPICAL	SPRAY	N
clobetasol propionate/emoll	CLOBETASOL EMOLLIENT	TOPICAL	CREAM (G)	N
clobetasol propionate/emoll	CLOBETASOL EMOLLIENT	TOPICAL	FOAM	N
clobetasol propionate/emoll	CLOBETASOL EMULSION	TOPICAL	FOAM	N
clobetasol propionate/emoll	OLUX-E	TOPICAL	FOAM	N

clobetasol propionate/emoll	TOVET EMOLLIENT	TOPICAL	FOAM	N
clobetasol/emollient no.65	TOVET KIT	TOPICAL	COMBO. PKG	N
clobetasol/skin cleanser no.28	CLODAN	TOPICAL	KT SHM CLN	N
clocortolone pivalate	CLOCORTOLONE PIVALATE	TOPICAL	CREAM (G)	N
clocortolone pivalate	CLODERM	TOPICAL	CREAM (G)	N
desonide	DESONIDE	TOPICAL	LOTION	N
desoximetasone	DESOXIMETASONE	TOPICAL	CREAM (G)	N
desoximetasone	TOPICORT	TOPICAL	CREAM (G)	N
desoximetasone	DESOXIMETASONE	TOPICAL	GEL (GRAM)	N
desoximetasone	TOPICORT	TOPICAL	GEL (GRAM)	N
desoximetasone	DESOXIMETASONE	TOPICAL	OINT. (G)	N
desoximetasone	TOPICORT	TOPICAL	OINT. (G)	N
desoximetasone	DESOXIMETASONE	TOPICAL	SPRAY	N
desoximetasone	TOPICORT	TOPICAL	SPRAY	N
diflorasone diacet/emollient	APEXICON E	TOPICAL	CREAM (G)	N
diflorasone diacetate	DIFLORASONE DIACETATE	TOPICAL	CREAM (G)	N
diflorasone diacetate	PSORCON	TOPICAL	CREAM (G)	N
diflorasone diacetate	DIFLORASONE DIACETATE	TOPICAL	OINT. (G)	N
fluocinolone acetonide	DERMA-SMOOTHE-FS	TOPICAL	OIL	N
fluocinolone acetonide	FLUOCINOLONE ACETONIDE	TOPICAL	OIL	N
fluocinolone acetonide	FLUOCINOLONE ACETONIDE	TOPICAL	OINT. (G)	N
fluocinolone acetonide	SYNALAR	TOPICAL	OINT. (G)	N
fluocinolone acetonide	CAPEX SHAMPOO	TOPICAL	SHAMPOO	N
fluocinolone/emol comb no.65	SYNALAR	TOPICAL	CMB ONT CR	N
fluocinolone/emol comb no.65	SYNALAR	TOPICAL	CREAM (G)	N
fluocinolone/shower cap	DERMA-SMOOTHE-FS	TOPICAL	OIL	N
fluocinolone/shower cap	FLUOCINOLONE ACETONIDE	TOPICAL	OIL	N
fluocinolone/skin clnsr28	SYNALAR TS	TOPICAL	KIT	N
fluocinonide	FLUOCINONIDE	TOPICAL	GEL (GRAM)	N
fluocinonide	FLUOCINONIDE	TOPICAL	OINT. (G)	N
flurandrenolide	FLURANDRENOLIDE	TOPICAL	CREAM (G)	N
flurandrenolide	FLURANDRENOLIDE	TOPICAL	LOTION	N
flurandrenolide	CORDRAN	TOPICAL	MED. TAPE	N
flurandrenolide	FLURANDRENOLIDE	TOPICAL	OINT. (G)	N
fluticasone propionate	FLUTICASONE PROPIONATE	TOPICAL	CREAM (G)	N
fluticasone propionate	BESER	TOPICAL	LOTION	N
fluticasone propionate	FLUTICASONE PROPIONATE	TOPICAL	LOTION	N
fluticasone propionate	FLUTICASONE PROPIONATE	TOPICAL	OINT. (G)	N
fluticasone/emollient no.65	BESER KIT	TOPICAL	KT LOTN CE	N

halcinonide	HALCINONIDE	TOPICAL	CREAM (G)	N
halcinonide	HALOG	TOPICAL	CREAM (G)	N
halcinonide	HALOG	TOPICAL	OINT. (G)	N
halcinonide	HALOG	TOPICAL	SOLUTION	N
halobetasol propionate	HALOBETASOL PROPIONATE	TOPICAL	CREAM (G)	N
halobetasol propionate	ULTRAVATE	TOPICAL	CREAM (G)	N
halobetasol propionate	HALOBETASOL PROPIONATE	TOPICAL	FOAM	N
halobetasol propionate	LEXETTE	TOPICAL	FOAM	N
halobetasol propionate	BRYHALI	TOPICAL	LOTION	N
halobetasol propionate	ULTRAVATE	TOPICAL	LOTION	N
halobetasol propionate	HALOBETASOL PROPIONATE	TOPICAL	OINT. (G)	N
halobetasol propionate	ULTRAVATE	TOPICAL	OINT. (G)	N
halobetasol/lactic acid	ULTRAVATE X	TOPICAL	CMB ONT CR	N
halobetasol/lactic acid	ULTRAVATE X	TOPICAL	COMBO. PKG	N
hydrocortisone	HYDROCORTISONE	TOPICAL	CREAM (G)	N
hydrocortisone	HYDROCORTISONE	TOPICAL	CREAM PACK	N
hydrocortisone	CETACORT	TOPICAL	LOTION	N
hydrocortisone	HYDROCORTISONE	TOPICAL	LOTION	N
hydrocortisone	HYDROCORTISONE	TOPICAL	LOTION	N
hydrocortisone	SCALP CORT	TOPICAL	LOTION	N
hydrocortisone	SCALP	TOPICAL	SOLUTION	N
hydrocortisone	SCALPICIN	TOPICAL	SOLUTION	N
hydrocortisone	TEXACORT	TOPICAL	SOLUTION	N
hydrocortisone	HYDROCORTISONE	TOPICAL	SPRAY	N
hydrocortisone acet/aloe vera	HYDROCORTISONE ACETATE W/ALOE	TOPICAL	CREAM (G)	N
hydrocortisone acet/aloe vera	HYDROCORTISONE W/ALOE	TOPICAL	CREAM (G)	N
hydrocortisone acet/aloe vera	HYDROCORTISONE ACETATE W/ALOE	TOPICAL	OINT. (G)	N
hydrocortisone acet/aloe vera	HYDROCORTISONE W/ALOE	TOPICAL	OINT. (G)	N
hydrocortisone acet/aloe vera	HYDROCORTISONE W/ALOE	TOPICAL	PACKET	N
hydrocortisone acetate	MICORT-HC	TOPICAL	CRM/PE APP	N
hydrocortisone acetate	HYDROCORTISONE	TOPICAL	OINT. (G)	N
hydrocortisone acetate	HYDROCORTISONE ACETATE	TOPICAL	OINT. (G)	N
hydrocortisone butyrate	HYDROCORTISONE BUTYRATE	TOPICAL	CREAM (G)	N
hydrocortisone butyrate	HYDROCORTISONE BUTYRATE	TOPICAL	LOTION	N
hydrocortisone butyrate	LOCOID	TOPICAL	LOTION	N
hydrocortisone butyrate	HYDROCORTISONE BUTYRATE	TOPICAL	OINT. (G)	N
hydrocortisone butyrate/emoll	HYDROCORTISONE BUTYRATE	TOPICAL	CREAM (G)	N
hydrocortisone butyrate/emoll	LOCOID LIPOCREAM	TOPICAL	CREAM (G)	N
hydrocortisone probutate	PANDEL	TOPICAL	CREAM (G)	N

hydrocortisone valerate	HYDROCORTISONE VALERATE	TOPICAL	CREAM (G)	N
hydrocortisone valerate	HYDROCORTISONE VALERATE	TOPICAL	OINT. (G)	N
hydrocortisone/aloe vera	ANTI-ITCH WITH ALOE	TOPICAL	CREAM (G)	N
hydrocortisone/aloe vera	HYDROCORTISONE PLUS	TOPICAL	CREAM (G)	N
hydrocortisone/aloe vera	HYDROCORTISONE W/ALOE	TOPICAL	CREAM (G)	N
hydrocortisone/aloe vera	HYDROCORTISONE-ALOE	TOPICAL	CREAM (G)	N
hydrocortisone/aloe vera	HYDROCORTISONE W/ALOE	TOPICAL	OINT. (G)	N
hydrocortisone/skin cleanser25	AQUA GLYCOLIC HC	TOPICAL	COMBO. PKG	N
mometasone furoate	MOMETASONE FUROATE	TOPICAL	CREAM (G)	N
mometasone furoate	MOMETASONE FUROATE	TOPICAL	OINT. (G)	N
mometasone furoate	MOMETASONE FUROATE	TOPICAL	SOLUTION	N
neomycin sulfate/fluocinolone	NEO-SYNALAR	TOPICAL	CREAM (G)	N
neomycin/fluocinolone/emoll 65	NEO-SYNALAR	TOPICAL	CREAM (G)	N
prednicarbate	PREDNICARBATE	TOPICAL	CREAM (G)	N
prednicarbate	PREDNICARBATE	TOPICAL	OINT. (G)	N
triamcinolone acetonide	KENALOG	TOPICAL	AEROSOL	N
triamcinolone acetonide	TRIAMCINOLONE ACETONIDE	TOPICAL	AEROSOL	N
triamcinolone acetonide	KENALOG	TOPICAL	LOTION	N
triamcinolone acetonide	TRIAMCINOLONE ACETONIDE	TOPICAL	LOTION	N
hydrocortisone	ANUSOL-HC	TOPICAL	CRM/PE APP	
hydrocortisone	HYDROCORTISONE	TOPICAL	CRM/PE APP	
hydrocortisone	PROCTO-MED HC	TOPICAL	CRM/PE APP	
hydrocortisone	PROCTOSOL-HC	TOPICAL	CRM/PE APP	
hydrocortisone	PROCTOZONE-HC	TOPICAL	CRM/PE APP	
neomycin sulfate/hydrocort	NEOMYCIN W/HYDROCORTISONE	TOPICAL	OINT. (G)	

Appendix 2: New Comparative Clinical Trials

A total of 44 citations were manually reviewed from the initial literature search. After further review, 43 citations were excluded because of wrong study design (e.g., observational), comparator (e.g., no control or placebo-controlled), or outcome studied (e.g., non-clinical). The remaining 2 trials are summarized in the table below. Full abstracts are included in **Appendix 3**.

Table 1. Description of Randomized Comparative Clinical Trials.

Study	Comparison	Population	Primary Outcome	Results	Notes/Limitations
Abdel L, et al[20] DB, RCT	1. Topical calcipotriol and betamethasone ointment once daily 2. Monochromatic excimer light twice weekly Duration: 12 weeks	Subjects aged 6 to 64 yo with NSV Mean age: 35 yo N=44	Repigmentation grade after 12 weeks of treatment of 2 stable vitiligo lesions	Percentage of repigmentation 1. 63.75% 2. 65% Difference between treatments: P = 0.23 (NS)	• Small sample size • Method of randomization not described • 18% of patients (n=8) did not complete all treatment sessions for unknown reasons • Repigmentation assessment conducted via visual analysis by 2 independent clinicians
Abbreviations: CI = confidence interval; DB = double blind; N = number; NB-UVB = narrow band ultra violet B; NSV = non-segmental vitiligo; NR = not reported; RCT = randomized clinical trial; VASI = vitiligo and activity scoring index; yo = years old					

Appendix 3: Abstracts of Comparative Clinical Trials

Monochromatic Excimer Light Versus Combination Of Topical Steroid With Vitamin D3 Analogue In The Treatment Of Nonsegmental Vitiligo: A Randomized Blinded Comparative Study[20]

Vitiligo is a difficult disease to treat, socially stigmatizing its patients. Monochromatic excimer light (MEL) was developed for use in dermatology and adapted for the treatment of vitiligo. Comparing the efficacy of MEL versus topical combination therapy of vitamin D3 analogue and steroid in the treatment of nonsegmental vitiligo. Forty-four patients with localized and stable nonsegmental vitiligo participated in the present study. In each patient, two lesions were selected and divided randomly into two groups, group A was treated with daily topical combination of calcipotriol and betamethasone and group B was treated with biweekly sessions of MEL for 3 months. Efficacy based on repigmentation percentages were blindly evaluated by two independent physicians and patient's satisfaction. There was significant improvement in both treatment modalities at the end of the study, but without significant differences in both groups. There was a significant difference between both groups regarding the onset of repigmentation (p-value < 0.05), whereas group B showed early sign of repigmentation in first 4 weeks of treatment in 16 patients versus 7 patients in group A. Both treatment modalities offered encouraging results and both are promising lines for the treatment of vitiligo.

Appendix 4: Prioritized List Guideline Note

Extracted from the January 1, 2022 Prioritized List
Searchable Prioritized List 2022

GUIDELINE NOTE 21, SEVERE INFLAMMATORY SKIN DISEASE
Lines 426,482,504,532,541,656

Inflammatory skin conditions included in this guideline are:

A) Psoriasis
B) Atopic dermatitis
C) Lichen planus
D) Darier disease
E) Pityriasis rubra pilaris
F) Discoid lupus
G) Vitiligo

The conditions above are included on Line 426 if severe, defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on other validated tool) AND one or more of the following:

C) At least 10% of body surface area involved
D) Hand, foot, face, or mucous membrane involvement.

Otherwise, these conditions above are included on Lines 482, 504, 532, 541 and 656.
For severe psoriasis, first line agents include topical agents, phototherapy and methotrexate. Second line agents include other systemic agents and oral retinoids and should be limited to those who fail, or have contraindications to, or do not have access to first line agents. Biologics are included on this line only for the indication of severe plaque psoriasis; after documented failure of first line agents and failure of (or contraindications to) a second line agent.

For severe atopic dermatitis/eczema, first-line agents include topical moderate- to high- potency corticosteroids and narrowband UVB. Second line agents include topical calcineurin inhibitors (e.g. pimecrolimus, tacrolimus), topical phosphodiesterase (PDE)-4 inhibitors (e.g. crisaborole), and oral immunomodulatory therapy (e.g. cyclosporine, methotrexate, azathioprine, mycophenolate mofetil, or oral corticosteroids). Use of the topical second line agents (e.g. calcineurin inhibitors and phosphodiesterase (PDE)-4 inhibitors) should be limited to those who fail or have contraindications to first line agents. Biologic agents are included on this line for atopic dermatitis only after failure of or contraindications to at least one agent from each of the following three classes: 1) moderate to high potency topical corticosteroids, 2) topical calcineurin inhibitors or topical phosphodiesterase (PDE)-4 inhibitors, and 3) oral immunomodulator therapy.

ICD-10-CM Q82.8 (Other specified congenital malformations of skin) is included on Line 426 only for Darier disease.

Appendix 5: Medline Search Strategy

Ovid MEDLINE(R) without Revisions 1946 to March Week 2 2022, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations 1946 to March 18, 2022

1	exp Vitiligo/cl, dt, ep, ge, pp, th [Classification, Drug Therapy, Epidemiology, Genetics, Physiopathology, Therapy]	2853
2	Glucocorticoids/ or Dermatitis, Atopic/ or topical glucocorticoids.mp. or Anti-Inflammatory Agents/	173169
3	Calcineurin Inhibitors/tu [Therapeutic Use]	650
4	2 or 3	173687
5	1 and 4	179
6	limit 5 to (english language and humans)	165
7	limit 6 to (clinical trial, all or clinical trial, phase iii or clinical trial or comparative study or controlled clinical trial or guideline or meta-analysis or multicenter study or practice guideline or pragmatic clinical trial or randomized controlled trial or "systematic review")	44

Appendix 6: Key Inclusion Criteria

Population	Adults and Children
Intervention	Topical corticosteroids and topical calcineurin inhibitors
Comparator	Placebo
Outcomes	Extent of repigmentation
Timing	2-3 months
Setting	Outpatient

Topical Agents for Inflammatory Skin Diseases

Goal(s):

- Restrict dermatological drugs only for funded OHP diagnoses. Treatments are funded on the OHP for severe inflammatory skin diseases including: psoriasis, atopic dermatitis, lichen planus, Darier disease, pityriasis rubra pilaris, discoid lupus and vitiligo. Treatments for mild or moderate psoriasis, mild or moderate atopic dermatitis, lichen planus, Darier disease, pityriasis rubra pilaris, discoid lupus and vitiligo seborrheic dermatitis, keratoderma and other hypertrophic and atrophic conditions of skin are not funded.

Length of Authorization:

- From 6 to 12 months

Requires PA:

- Non-preferred antipsoriatics
- All atopic dermatitis drugs
- STC = 92 and HIC = L1A, L5F, L9D, T0A
- This PA does not apply to targeted immune modulators for psoriasis or atopic dermatitis which are subject to separate clinical PA criteria.

Covered Alternatives:

- Preferred alternatives listed at www.orpdl.org/drugs/

Table 1. FDA-approved ages for atopic dermatitis drugs

Drug	Minimum Age
Crisaborole	3 months
Pimecrolimus	2 years
Ruxolitinib	12 years
Tacrolimus 0.03%	2 years
Tacrolimus 0.1%	16 years

Approval Criteria		
1. What diagnosis is being treated?	Record ICD 10 code.	
2. Is the diagnosis for mild or moderate inflammatory skin conditions?	**Yes:** Pass to RPh; deny, not funded by the OHP.	**No:** Go to #3
3. Is the request for treatment of severe inflammatory skin disease? Severe disease is defined as:[1] • Having functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on other validated tool) AND one or more of the following: 1. At least 10% body surface area involved OR 2. Hand, foot, face, or mucous membrane involvement	**Yes:** Go to #4	**No:** Pass to RPh; deny, not funded by the OHP
4. Is the diagnosis psoriasis?	**Yes:** Go to #8	**No:** Go to #5
5. Is the diagnosis atopic dermatitis?	**Yes:** Go to #6	**No:** Go to #10
6. Does the patient meet the age requirements per the FDA label (Table 1)?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
7. Does the patient have a documented contraindication, intolerance or failed trials of at least 2 first line agents (i.e. topical corticosteroids, tacrolimus) indicated for the treatment of severe AD? *Note ruxolitinib, pimecrolimus and crisaborole are FDA approved to manage mild to moderate AD, while tacrolimus is FDA approved to manage moderate to severe AD.	**Yes:** Document drug and dates trialed, and intolerances or contraindications (if applicable): 1._____(dates) 2._____(dates) Approve for length of treatment; maximum 6 months.	**No:** Pass to RPh. Deny; medical appropriateness
8. Is the requested product preferred?	**Yes:** Approve for length of treatment; maximum 1 year.	**No:** Go to #9
9. Will the prescriber consider a change to a preferred product? **Message:** Preferred products are evidence-based reviewed for comparative effectiveness & safety by the Pharmacy and Therapeutics (P&T) Committee.	**Yes:** Inform provider of preferred alternatives. Approve for length of treatment; maximum 1 year.	**No**: Approve for length of treatment; maximum 1 year.
10. RPH only: All other indications need to be evaluated as to whether they are funded by the OHP.*	**If funded, and clinic provides supporting literature:** Approve for 1 year.	**If not funded:** Deny, not funded by the OHP.

P&T/DUR Review: *6/22 (DM); 12/20; 10/20; 7/19; 5/19; 3/18; 9/17; 7/15; 1/15; 09/10; 9/09; 3/09; 5/07; 2/06*
Implementation: *7/1/22; 1/1/2021, 11/1/20; 8/19/19; 4/16/18; 10/15; 8/15; 9/13; 6/12; 9/10; 1/10; 7/09; 6/07; 9/06*

**The Health Evidence Review Commission has stipulated via Guideline Note 21 that mild and moderate uncomplicated inflammatory skin conditions including psoriasis, atopic dermatitis, lichen planus, Darier disease, pityriasis rubra pilaris, and discoid lupus are not funded. Uncomplicated is defined as no functional impairment; and/or involving less than 10% of body surface area and no involvement of the hand, foot, face or mucous membranes.*

Reference:

1.Oregon Health Evidence Review Commission. Coverage Guidance and Reports. http://www.oregon.gov/oha/hpa/csi-herc/pages/index.aspx Accessed March 1, 2022.

Section 7.0

New Discussion Items

Corneal Collagen Cross-Linkage

Plain Language Summary:
Background: Should a treatment for a condition which results in vision problems from thinning of the outer layer of the eye (cornea) be covered on the Oregon Health Plan?

Should OHP cover this treatment? Staff recommends covering this treatment because evidence shows the treatment works for certain conditions.

Question: Should corneal collagen cross-linkage be added as a treatment of keratoconus?

Question source: Holly Jo Hodges, CCO medical director

Issue: Keratoconus is a corneal thinning disorder occurring when the normally round dome-shaped cornea, the clear tissue covering the front of the eye, progressively changes shape to a conical bulge. This causes refractive error, which is usually a myopic shift and is often associated with astigmatism, leading to visual impairment. It commonly affects children and young adults and may be progressive.

In mild to moderate keratoconus, clinical management to correct visual acuity is by glasses or contact lenses. With disease progression, rigid gas permeable contact lenses may be fitted or corneal ring segment inserts used. However, if the corneal shape deteriorates further some form of corneal surgery may be required, including deep lamellar keratoplasty or penetrating keratoplasty for severe progressive keratoconus. Corneal collagen cross-linkage (CXL) using riboflavin and ultraviolet A (UV A) radiation was piloted on patients in 2003. It increases corneal biomechanical stiffness thereby strengthening and stabilizing the cornea. This is achieved by increasing the number of 'anchors' that bond collagen fibers together. The aim is to stop disease progression and need for corneal transplant.

Current Prioritized List status
Never Reviewed:
CPT 0402T Collagen cross-linking of cornea (including removal or the corneal epithelium and intraoperative pachymetry when performed)

ICD-10-CM H18.6 family (keratoconus) is on line 310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA with various surgical treatments paired

Evidence:

1) **NICE 2013** systematic review on photochemical corneal collagen cross-linkage
    a. N=49 papers on efficacy and N=26 papers on safety
        i. Generally given a grade of low or very low quality
    b. Improvements in measures of topography were found for Max K, mean K and Min K, respectively at 6, 12 months and 24 months. Benefit increased to 12 months and then stabilized. This evidence came from a comparison of baselines before and after procedure; no randomized control data were available.
    c. For measures of visual acuity, meta-analysis of change between treated and control groups at 12 months found no significant differences for uncorrected visual acuity but a significant difference of around -0.20 (LogMAR) for corrected visual acuity. One RCT reporting at 18 months only, however, found non-significant differences between the

treatment and control groups in corrected visual acuity. The results for differences between post-treatment and baseline values for treated patients showed significant improvements for corrected and uncorrected visual acuity at 6, 12 and 24 months. Improvement was also indicated by the results from all papers reporting this outcome.

d. No significant differences were found between the treatment and control groups for measures of astigmatism. Differences between post-treatment and baseline values for treated patients showed statistically significant improvements in astigmatism at 6, 12 and 24 months, and for spherical equivalence measures, significant differences at 12 months.
e. A meta-analysis of 6 papers found a statistically significant reduction in central corneal thickness values between post-treatment and baseline values for treated patients at 12 months. Evidence from 25 papers was supportive of a reduction.
f. Evidence on intraocular pressure is poor but suggestive of a tendency to higher intraocular pressure after procedure.
g. The procedure is generally reported as safe but serious complications were reported, including the need for 4 patients to have corneal transplant, and a similar number suffering long-term loss in visual acuity. Cause of the events was seldom disclosed. For example, some infections may be due to the patient failing to comply with advice on after care, while other events may be due to operator error. Most events resolved over time with no major consequences for the patient.

Other payer policies:

1) NICE 2013

a. Current evidence on the safety and efficacy of epithelium-off CXL for keratoconus and keratectasia is adequate in quality and quantity. Therefore, this procedure can be used provided that normal arrangements are in place for clinical governance, consent and audit
b. Current evidence on the safety and efficacy of epithelium-on (transepithelial) CXL, and the combination (CXL-plus) procedures for keratoconus and keratectasia is inadequate in quantity and quality. Therefore, these procedures should only be used with special arrangements for clinical governance, consent and audit or research

2) Aetna 2022

a. Aetna considers epithelium-off photochemical collagen cross-linkage using riboflavin (Photrexa) and ultraviolet A medically necessary for keratoconus and keratectasia.
b. Aetna considers photochemical collagen cross-linkage experimental and investigational for all other indications because its effectiveness for other indications has not been established.
c. Aetna considers epithelium-on (transepithelial) collagen cross-linkage experimental and investigational for keratoconus, keratectasia, and all other indications.
d. Aetna considers performance of photochemical collagen cross-llinkage in combination with other procedures (CXL-plus) (e.g., intrastromal corneal ring segments, PRK or phakic intra-ocular lens implantation) experimental and investigational.

3) Cigna 2021

a. Conventional, epithelium-off, corneal collagen crosslinking (C-CXL) using a U.S. Food and Drug Administration (FDA) approved drug/device system (e.g., Photrexa® Viscous or Photrexa® with the KXL® System) (CPT Code® 0402T; HCPCS Code J2787) is considered medically necessary for the treatment of EITHER of the following:

i. progressive keratoconus
ii. corneal ectasia following refractive surgery
iii. when ALL of the following criteria are met:
1. age 14–65 years
2. progressive deterioration in vision
3. absence of visual disturbance from a significant central corneal opacity or other eye disease (e.g., herpetic keratitis, neurotrophic keratopathy)

b. C-CXL is considered experimental, investigational or unproven for any other indication including when combined with a second refractive procedure. All other corneal collagen crosslinking procedures (e.g., epithelium-on/trans-epithelial) are considered experimental, investigational or unproven.

4) Blue Cross/Blue Shield

a. Corneal collagen cross-linking using riboflavin and ultraviolet A may be considered medically necessary as a treatment of:
   i. progressive keratoconus OR
   ii. corneal ectasia after refractive surgery in patients who have failed conservative treatment (eg spectacle correction, rigid contact lens).

b. Progressive keratoconus or corneal ectasia is defined as one or more of the following:
   i. An increase of 1 diopter (D) in the steepest keratometry value;
   ii. An increase of 1 D in regular astigmatism evaluated by subjective manifest refraction;
   iii. A myopic shift (decrease in the spherical equivalent) of 0.50 D on subjective manifest refraction;
   iv. A decrease ≥0.1 mm in the back optical zone radius in rigid contact lens wearers where other information was not available.

<u>Expert input</u>

Dr. Travis Redd, OHSU ophthalmology

I strongly support OHP providing CXL coverage. It would make a huge positive impact for our patients.

Dr. Winston Chamberlain, OHSU ophthalmology

This is very important topic to us because many of our patients are not getting access to vision saving care because of OHP's current lack of coverage policy for crosslinking. The problem is bad enough that many OHP patients have lost vision or required more expensive and more risky procedures…The procedure is not inexpensive because of J codes required to Cover the medication under the current approval status of the procedure in the United States and the equipment and facility costs. But it is a fraction of the cost of the alternative procedure that OHP has historically forced us to consider which is a corneal transplant with lifelong risks to patients and maintenance.

Corneal Collagen Cross-Linkage

HERC staff summary

Corneal collagen cross linking has limited evidence of effectiveness for treatment of progressive keratoconus based on trusted evidence sources. This procedure is covered by all major insurers surveyed for progressive keratoconus or corneal ectasia following refractive surgery when there is a progressive deterioration in vision. Experts recommend coverage as vision saving cost-effective care.

HERC staff recommendations:

1) Add CPT 0402T (Collagen cross-linking of cornea (including removal or the corneal epithelium and intraoperative pachymetry when performed)) to line 310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA
2) Adopt a new guideline for line 310 as shown below

GUIDELINE NOTE XXX CORNEAL COLLAGEN CROSS LINKING

Line 310

CPT 0402T is included on this line only when use for conventional, epithelium-off, corneal collagen crosslinking and only for treatment of

1) progressive keratoconus OR
2) corneal ectasia following refractive surgery; and

only when there is progressive deterioration in vision.

YHEC
York Health Economics Consortium

The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

Providing consultancy and research in health economics for the NHS, pharmaceutical and health care industries since 1986

INTERVENTIONAL PROCEDURE ADVISORY COMMITTEE

Photochemical Corneal Collagen Cross-Linkage Using Riboflavin and Ultraviolet A for Keratoconus: A Systematic Review

Produced by NUTH and YHEC
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MAY 2013

THE UNIVERSITY of York

INVESTORS IN PEOPLE

Executive Summary

1. BACKGROUND

The systematic review is of two groups of patients, namely those with a diagnosis of keratoconus or keratectasia.

Keratoconus is a corneal thinning disorder occurring when the normally round dome-shaped cornea, the clear tissue covering the front of the eye, progressively changes shape to a conical bulge. Thinning occurs primarily in the stroma layers and one potential explanation for this a defect in the collagen process.

Keratoconus has a prevalence of under 0.05% (1 in 2,000) of the population, with an earlier onset than most chronic eye diseases with a patient median age of 25 years. Those with the disease suffer a loss in visual acuity, making tasks such as driving, reading and screen work difficult.

Keratoconus can also be secondary, resulting from an infrequent but serious complication of laser-assisted *in situ* keratomileusis (LASIK) surgery, and is then called keratectasia. If the cornea's structure is weakened during LASIK surgery, it can bulge forward in an irregular fashion, causing increasing astigmatism and distorted vision. This cannot be corrected with spectacles, contact lenses, or a LASIK enhancement procedure. Patients with thin corneas prior to LASIK have a higher risk of developing keratectasia. The treatment pathway is similar to that for keratoconus.

Diagnosis of keratoconus is often not straightforward and typically requires a review of family history, looking for clinical signs, and use of various instruments to measure corneal topography and central corneal thickness. The management of keratoconus depends on the stage of the disease. The stage can be identified using the Amsler-Krumeich classification which has 4 stages from mild (grade I) to severe (grade IV).

In mild to moderate keratoconus, clinical management to correct visual acuity is by spectacles or contact lenses. With disease progression, rigid gas permeable contact lenses may be fitted or corneal ring segment inserts used. However, if the corneal shape deteriorates further some form of corneal surgery may be required, including deep lamellar keratoplasty or penetrating keratoplasty for severe progressive keratoconus.

Prior to introduction of corneal collagen cross-linkage (CXL), no interventions were available to arrest or slow disease progression, with corneal transplantation required in up to 21% of keratoconic eyes. Visual acuity may not be fully restored after transplant and the disease may recur, requiring subsequent interventions.

CXL using riboflavin and ultraviolet A (UV A) radiation was piloted on patients in 2003. It increases corneal biomechanical stiffness thereby strengthening and stabilising the cornea. This is achieved by increasing the number of 'anchors' that bond collagen fibres together. The aim is to stop disease progression.

With 'epithelium-off cross-linkage', the epithelium is removed with a blunt spatula or laser. Riboflavin eye drops are applied to the corneal surface 5 minutes before the procedure to enable penetration into the corneal tissue and then every 3 to 5 minutes during the procedure. The corneal surface is exposed to the UV A radiation, usually for up to 30 minutes. Postoperatively, topical antibiotics and anti-inflammatory drops will normally be prescribed with topical steroids if necessary. In some cases, a bandage contact lens may

also be used for a few days. The outpatient procedure takes 60 to 90 minutes in most cases.

With transepithelial corneal cross-linkage (epithelium-on) the corneal epithelial surface is left intact, which requires a longer riboflavin loading time but may reduce the risk of infection.

CXL can be used in conjunction with various techniques designed to improve visual acuity. Adjunct procedures include:

- A range of corneal implants, also known as intracorneal ring segments (ICRS);
- Topography-guided and other forms of photorefractive keratectomy (PRK), a form of laser ablation;
- Phakic intraocular lens (PIOL).

The most common complications reported after the procedure are stromal haze, which usually resolves, and pain. More serious events include infection, corneal melting, perforation and ulceration, and stromal scarring.

2. OBJECTIVE

The objective of this systematic review is to examine evidence for the efficacy and safety of CXL using riboflavin and ultraviolet A for keratoconus and keratectasia, alone or in combination with interventions designed to improve visual acuity. These combination interventions are referred to as 'CXL-Plus'.

The evidence will allow the Interventional Procedures Advisory Committee to reassess guidance on the procedure. This was originally issued in November 2009 by the National Institute for Health and Clinical Excellence (NICE). This recommended that, given inadequate evidence, the procedure should only be used with special arrangements for clinical governance, consent and audit or research. Subsequently, new evidence has been published.

3. LITERATURE SEARCH AND SYNTHESIS OF PAPERS

The systematic review adopted a search strategy designed to identify all relevant published, unpublished and grey literature. A date limit of 2000 to 31 October 2012 was applied. The search returned 1,747 abstracts, after removal of duplicates. Inclusion criteria were:

- English-language reports and human studies;
- Patients with keratoconus or keratectasia;
- Reports with interventions using photochemical corneal collagen cross-linkage using riboflavin and ultraviolet alone, or in combination or sequence with other treatments;
- Original reports with defined study methodology;
- Reports including standardised measurements on outcome events such as technical access, safety, efficacy, durability, vision, quality of life or patient satisfaction;
- Systematic reviews, meta-analyses, randomised controlled trials, observational studies, retrospective analyses, case series, case studies, letters, comments and conference abstracts.

These eligibility criteria were applied to abstracts and titles to inform provisional study selection. Two researchers reviewed the retrieved abstracts and titles, for those with no abstract, and made their selections independently. Differences were reconciled by mutual

agreement. Two hundred and fifteen papers were selected by agreement, 17 were in a foreign language and not retrieved, and a further 8 papers could not be obtained. The remaining 190 papers were retrieved.

The inclusion and exclusion criteria were applied to the full papers to judge which should be included in this study. Seventy-one papers on efficacy and 26 on adverse events were selected for full data extraction, with 93 papers excluded. Of these, 19 were efficacy studies with fewer than 10 patients or less than 6 months follow-up; these were partially extracted and reported as an appendix, but not considered in the analysis. Full data extraction was undertaken on the 71 efficacy papers and a more limited extraction on the 26 papers on safety events.

Formal meta-analyses were undertaken on publications reporting results using the epithelium-off procedure. Extracted data showing effect sizes, study end points and time periods were reviewed and any inconsistencies or unexpected results checked by going back to original papers. The relevant end points agreed with NICE were:

- Change in visual acuity;
- Change in topography;
- Change in refraction and astigmatism;
- Change in intraocular pressure;
- Change in central corneal thickness.

Where sufficient data were available across common time periods they were synthesised using meta-analysis based on both random effects and fixed effects models. Heterogeneity was identified by using the I^2 statistic. Meta-analysis results were reported using forest plots.

For CXL-Plus interventions and the transepithelial corneal cross-linkage (epithelium-on) procedure, a narrative synthesis of the same end points was undertaken.

4. RESULTS

4.1 Evidence on epithelium-off CXL

Identified evidence comprised 49 papers on the efficacy of epithelium-off CXL and 26 on the safety of epithelium-off CXL. Of the 49 efficacy papers, 8 were randomised controlled trials (RCTs), reporting 4 unique studies with the main comparator being fellow-eyes; the exception was an Australian RCT which did randomise eyes matched for disease status. Only preliminary results have been reported from that study.

The remaining papers reported changes before and after the procedure, which limits the ability to draw conclusions on the causal nature of the effect presented. However, given the disease is progressive, evidence of halting progression or indeed reversing it is supportive of a beneficial effect.

Of the non-RCT papers, the majority (25) were prospective case series, usually with well-defined inclusion criteria and trial design. However, few papers reported drop-out rates or reasons for them, thereby limiting the strength of the evidence.

Seven of the remaining papers were retrospective reviews, often using patient records as the data source. Using such data has strengths including that of reflecting actual outcomes in settings which may be similar to those of the NHS and are, thus, representative of clinical practice. However, there was concern about potential for bias in patient selection.

Almost 60% of papers were set in European tertiary centres, with a further 15% set in the USA; all sites undertook very similar CXL procedures. These settings are anticipated to be comparable to NHS settings. Two papers explicitly excluded patients with Amsler-Krumeich scale grade IV; otherwise the main inclusion criterion was progressive keratoconus. Thuse, there were no major concerns about the external validity of the results to a UK setting.

Overall, 39 papers were graded as very low evidence, six as low and four moderate. Those graded moderate reported on 4 RCTs but, as noted, these do not provide comparative evidence in eyes with progressive keratoconus.

Summary of findings from epithelium-off CXL papers

As noted, meta-analyses were conducted when sufficient data were reported for consistent end-points and time periods. To enable results for papers which could not be formally synthesised to be captured, a simple arithmetic mean across time periods was calculated. The results were grouped into consistent end points and by time period: 6, 12 and 24 months. Papers reporting at 9 months were included under the 12-month period and those reporting at 18 months under the 24-month period to avoid removing evidence. Papers reporting end points where the units measured were unclear or used measures which could not be aggregated with others were not included. The remaining results were used to calculate the mean value of the change reported for each end point/time period combination.

These assumptions and methodology were adopted for all parameters. The estimates are not offered as a precise estimate of the change in measures as a result of CXL, rather they give an indication of the size effect and its direction. They are intended to display the trend in evidence for each group of similar parameters but do no more than that.

Many meta-analyses displayed moderate to high heterogeneity across papers, giving wide confidence intervals, which suggests the studies were not consistent in their conduct.

Topography

Due to a lack of data, no meta-analyses of change between treated and control groups could be undertaken for measures of topography. Meta-analysis results for differences between post-treatment and baseline values for treated patients reported significant improvements for Max K (maximum keratometry) at 6, 12 and 24 months; these improvements were -0.8 dioptres (D) at 6 months and around -1.0 D at 12 and 24 months. For Min (minimum) K and mean K, meta-analysis was only undertaken at 6 and 12 months. Meta-analysis results were only significant at 12 months; average changes of around -1.0 D and -0.7 D were found for mean K and Min K, respectively.

The number of papers synthesized was for:

- Max K: 10, 18 and 6 papers at 6, 12 and 24 months, respectively;
- Min K: 4 and 8 papers at 6 and 12 months, respectively;
- Mean K: 7 and 12 papers at 6 and 12 months, respectively.

In total, 38 papers reported 104 comparable measures of topography over the three time periods, with 41 (38%) reporting statistically significant improvements in K values. The improvement increased over time with 4 papers reporting statistically significant differences at 12 months but not at 6 months. Of the 8 papers reporting data at 12 and 24 months, the 24-month values showed an improvement or no change on the 12-month values in all cases but one. One paper reporting a longer follow-up showed the improvement continued into year 3 and was then maintained to year 6. However, the number of patients lost to follow-up was large, thereby limiting the weight attributed to these results.

No precise estimate of the benefit across all papers is possible. However, a simple arithmetic mean calculated from the 104 measures gave an improvement of 1.5 D for Max K, 1.4 D for mean K and 1.1 D for Min K at 12 months, which were slightly higher than the meta-analyses results.

Visual acuity

Due to a lack of data, a meta-analysis of change between treated and control groups was only undertaken for visual acuity at 12 months. Only 3 studies contributed to the meta-analysis of corrected visual acuity and only two to the meta-analysis of uncorrected visual acuity. No significant difference was found between treatment and control groups for uncorrected visual acuity, whereas a significant difference of around -0.20 (LogMAR) was found for corrected visual acuity.

Differences between treatment and control groups over time were not significant for uncorrected visual acuity. For corrected visual acuity, there seemed to be an improvement over time, as the difference between treatment and control groups was not significant at 3 months but was so at both 6 and 12 months (-0.12 and -0.19 LogMAR, respectively). However, non-significant differences were reported at 18 months between treatment and control groups.

Based on results for differences between post-treatment and baseline values for treated patients, significant improvements were reported for corrected and uncorrected visual acuity at 6, 12 and 24 months. These were calculated using data from 12, 18 and 6 papers for uncorrected visual acuity and 15, 22 and 7 papers for corrected visual acuity, at 6, 12, and 24 months, respectively. Improvements on the LogMAR scale were in the order of -0.15 for uncorrected visual acuity and -0.10 for corrected visual acuity across the various time points.

In total, 38 papers reported 104 usable results on visual acuity of which 52 (50%) reported significant improvements in visual acuity. Arithmetic means of the differences calculated from this larger data set were similar to those from the meta-analyses. For uncorrected and corrected visual acuity the estimated benefit at 12 months was 0.19 and 0.10, respectively, on the LogMAR scale.

Astigmatism and cylinder measures

Due to a lack of data, meta-analysis was only undertaken for grouped astigmatism measured at 12 months. Only 2 studies contributed and no significant differences between treatment and control groups were found from the random effects model.

Meta-analysis results for differences between post-treatment and baseline values for treated patients showed statistically significant improvements in astigmatism at 6, 12 and 24 months, in the order of -0.4 D at 6 months, -0.7 D at 12 months and -0.5 D at 24 months. For spherical equivalence, meta-analysis was only undertaken at 6 and 12 months. The meta-analysis results, which were only significant at 12 months, showed a reduction of between 0.3 and 0.5 D.

These analyses included 7, 13 and 5 papers on astigmatism at 6, 12 and 24 months, respectively, and 8 and 10 papers on spherical equivalence at 6 and 12 months, respectively.

In total, 31 papers provided 88 usable results of astigmatism and refraction measures, of which 21 (23%) were statistically significant. Eleven values reported in 8 papers were negative (increase in a negative value), showing deterioration in the measure, but none were statistically significant. Analysing the usable results from all papers provided estimates of the reduction at 12 months of:

- 0.9 D for astigmatism, somewhat higher than the value from meta-analysis;
- 1.0 D in spherical equivalence.

Central corneal thickness

Due to a lack of data, no meta-analyses of change between treated and control groups could be undertaken for central corneal thickness. Two meta-analyses of data from 6 papers estimated differences in central corneal thickness values between post-treatment and baseline values for treated patients at 6 and 12 months. A significant decrease of 14 µm in central corneal thickness was found at 12 months. No significant difference was found in the meta-analysis of 6-month results.

In total, 25 papers reported on central corneal thickness measurements, of which three noted no statistical differences at any time period and two reported statistically significant reductions at 12 months. The arithmetic means of the changes across 23 papers at 6 and 12 months were -12 µm and -8 µm respectively, which support the results of the meta-analyses.

One paper reported changes in central corneal thickness for patients with keratoconus and keratectasia. Patients with keratectasia regained the pre procedure level of central corneal thickness at 12 months, whilst patients with keratoconus had a reduced central corneal thickness of about 6 µm.

Intraocular pressure

No meta-analyses of change between treated and control groups could be undertaken for intraocular pressure. Following clinical advice, only 2 studies were included in an analysis of differences between post-treatment and baseline values for treated patients, and this was undertaken at 6 months only. No significant differences were found.

Four papers stated that intraocular pressure was unchanged over all time periods, and one reported a statistically significant increase in intraocular pressure at 12 months of 2.9 mmHg. This was the only statistically significant value reported. Overall, 3 negative values with a mean value of -0.3 mmHg were reported, compared with 11 positive values with a mean value of 0.8 mmHg.

Adverse events and complications

Table 1 summarises adverse events reported in the 49 efficacy studies and 26 safety papers. In total, 40 serious complications were reported in 39 patients. To address events which did not resolve, 4 patients had corneal transplants and one an unspecified procedure. Four patients suffered reduced visual acuity and 6 had unresolved corneal oedema. In the other patients there were no major long-term complications. Some adverse events may be due to poor after care compliance by the patient and others may be site specific. For example, the 4 transplants were reported in one paper which was set in multiple centres in France.

Several studies reported pain, corneal oedema and corneal haze as common side effects. Sterile keratitis was reported in 20 patients. Other minor complications included striae, Descemet, blepharitis, endothelial irregularities and mild photophobia. These resolved over time.

Plain Language Summary:
Background: Clarify the Commission's intent for coverage of treatments and preventive services like vaccines when a public health emergency is declared. Previously, the Commission added guidelines for the Oregon Health Plan to address influenza.

Should OHP cover this treatment? Staff recommends creating a new Statement of Intent (SOI) to address public health emergency outbreaks.

Question: Should a new statement of intent (SOI) be adopted that indicates that the HERC intends to cover the necessary treatments/prophylactic care for public health outbreaks?

Question source: HERC staff

Issue: During the 2017 Legislative session, House Bill (HB) 3276 was passed mandating that private insurers cover the "necessary antitoxins, serums, vaccines, immunizing agents, antibiotics, antidotes and other pharmaceutical agents, medical supplies or other prophylactic measures approved by the United States Food and Drug Administration deemed necessary to prevent the spread of the disease, epidemic or other condition of public health importance."

From HB3276
If the director determines that there exists a disease outbreak, epidemic or other condition of public health importance in a geographic area of this state or statewide, an insurer shall, for enrollees in a health benefit plan offered by the insurer, reimburse the cost of necessary antitoxins, serums, vaccines, immunizing agents, antibiotics, antidotes and other pharmaceutical agents, medical supplies or other prophylactic measures approved by the United States Food and Drug Administration that the director deems necessary to prevent the spread of the disease, epidemic or other condition of public health importance**.**

A Prioritized List guideline was adopted in 2011 during the avian flu epidemic which specifically deals with treatment/prophylaxis of influenza.

> **GUIDELINE NOTE 87, INFLUENZA**
> *Line 404*
> Treatment and post-exposure prophylaxis of influenza should comply with state and national public health recommendations.

After HB 3276 passed, an OHA-led taskforce met in August of 2017 and published recommendations related to public health emergencies in October, 2017. They developed 8 recommendations; the 2 recommendations relevant to the Prioritized List were:

Task Force recommendations with the greatest support

- OHA should explore Medicaid options (for instance, state plan amendment or waiver and presumptive eligibility) with respect to an epidemic or other condition of public health importance for measures included in HB 3276.

- OHA should establish rules and guidelines that assure Oregon Health Plan member access to services as a result of a disease outbreak, epidemic or other condition of public health importance regardless of in-network status, with payment assured to any Medicaid provider including pharmacies, local health departments and student health centers.

Adopting a statement of intent regarding public health emergencies was discussed at VBBS/HERC in 2018. At that time, there was concern about the definition of public health emergency and who at the state had the power to declare a public health emergency. There was also concern about the lack of evidence for some treatments used for diseases that are considered public health emergencies. There was also concern about including the wording "approved by the United States Food and Drug Administration" in the proposed guideline as many emergency treatments are not approved by the FDA and other treatments with FDA approval are not necessarily effective or strongly evidence based. The HERC requested that staff work on more clearly defining the terms used in this guideline and work with public health staff to ensure that the language of any statement of intent comply with the law.

HERC staff have worked with public health colleagues to obtain more information about the law on coverage of treatments for public health emergencies.

The wording in ORS based on the house bill is as follows:

> If the director determines that there exists a disease outbreak, epidemic or other condition of public health importance in a geographic area of this state or statewide, an insurer shall, for enrollees in a health benefit plan offered by the insurer, cover the cost of necessary antitoxins, serums, vaccines, immunizing agents, antibiotics, antidotes and other pharmaceutical agents, medical supplies or other prophylactic measures approved by the United States Food and Drug Administration that the director deems necessary to prevent the spread of the disease, epidemic or other condition of public health importance.

The director is defined as the public health director at OHA. Disease outbreak, epidemic and other condition of public health importance are defined in ORS 431A.005:

1) "Condition of public health importance" means a disease, syndrome, symptom, injury or other threat to public health that is identifiable on an individual or community level.
2) "Disease outbreak" means a significant or notable increase in the number of cases of a disease or other condition of public health importance.
3) "Epidemic" means the occurrence in a community or region of a group of similar conditions of public health importance that are in excess of normal expectancy and derived from a common or propagated source.

HERC staff recommendations:

1) Adopt a new statement of intent as shown below

STATEMENT OF INTENT XX, PUBLIC HEALTH EMERGENCIES

It is the intent of the Commission that If the state Public Health Director determines that there exists a disease outbreak, epidemic or other condition of public health importance in a geographic area of this state or statewide, under ORS 743A.264, then all necessary antitoxins, serums, vaccines, immunizing agents, antibiotics, antidotes and other pharmaceutical agents, medical supplies or other prophylactic measures approved or with emergency use authorization by the United States Food and Drug Administration that the director deems necessary to prevent the spread of the disease, epidemic or other condition of public health importance should be covered.

Solid Organ Transplants

Plain Language Summary:
Background: General review of current coverage and guidelines in organ transplants (for example, heart, lung, liver) other than bone marrow. This is an in-depth review of transplants overed on the Oregon Health Plan (OHP).

Should OHP cover this treatment? Staff recommends adding a new guideline for OHP that puts all current guidelines together and clarifies coverage. Staff also recommends adding and deleting select diagnosis codes on the transplant lines to help clarify coverage.

Questions:

1) Should the solid organ transplant lines be modified or merged?
2) Should a new guideline be adopted regarding solid organ transplants?

Question source: HERC staff

Issue: The current solid organ transplant lines have not been reviewed in depth in many years. The current lines do not contain all the possible diagnoses which might require transplant. There are several transplant lines for the same organ, depending on the indication. It is confusing to current staff why transplants of the same organ have different line scoring depending on the reason for the organ failure.

Additionally, some types of transplants have guidelines regarding when they are covered, but there is no guideline for several other types of transplants, such as heart or lung. Years ago, there was a flow chart guideline on the Prioritized List regarding when transplants should be covered based on expected years of life gained, but this was removed. For many years, HERC staff and the HERC have had a general sense that if the transplant is indicated by UNOS or the transplant center, then it is covered, other than very specific organs such as pancreas. Current transplant lines and guidelines are shown in Appendix A.

The current OHA transplant rules are very out of date. They are undergoing extensive modification and this review will be helpful input to that process.

HERC/HSC review history

1) Intestinal transplants
    a. Review and update done in January of 2020; a new guideline was added to the intestinal transplant line
2) Pancreatic transplant
    a. Pancreatic transplant alone (not concurrent with renal transplant) for type 1 diabetes was reviewed November 2018 and no change in non-coverage recommended
    b. Autologous islet cell transplant reviewed August 2019
        i. Allogenic islet cell transplant added to line 662
        ii. Autologous islet cell transplant added to the uncovered line for coverage with total pancreatectomy with a new guideline
3) Pancreas-kidney transplants
    a. Reviewed in August 2012. New guideline added
4) Lung transplant
    a. Reviewed in 2012 as part of the ICD-10 conversion review

   i. Two lung transplant lines combined into one, diagnoses reviewed and no new diagnoses proposed for addition by experts

5) Heart transplant
   a. Reviewed in 2012 as part of the ICD-10 conversion review
   b. Some diagnoses were added or removed
6) Liver transplant
   a. Last reviewed May 2019 but only for liver cancer which was at that time an uncovered indication for transplant
   b. New line created for liver transplant for liver cancer
7) Corneal transplant
   a. No mention found in review of minutes for corneal transplant, CPT 65710, or keratoplasty

Current prioritization scoring (all lines are category 6)

Line	Organ	HLY	Suffering	Pop effects	Vuln Pop	Tertiary Prev	Effectiveness	Need	Score
83	Pancreas, Pancreas/Kidney	8	3	0	0	4	4	1	2400
99	Kidney	7	2	0	0	5	4	1	2240
162	Liver	10	2	0	0	0	4	1	1920
239	Intestine, Intestine/Liver	10	4	0	0	4	2	1	1440
240	Heart/Lung, Lung	8	4	0	0	0	3	1	1440
241	Liver	9	3	0	0	0	3	1	1440
263	Liver	7	4	0	0	0	3	1	1320
264	Heart, Heart/Kidney	7	4	0	0	0	3	1	1320
307	Liver, Liver/Kidney	7	2	0	0	0	3	1	1080
310	Cornea	6	3	0	0	4	4	1	1040
563	Liver	7	4	0	0	0	1	0.1	44

83 DIABETES MELLITUS WITH END STAGE RENAL DISEASE
99 END STAGE RENAL DISEASE
162 BILIARY ATRESIA
239 SHORT BOWEL SYNDROME
240 CONDITIONS REQUIRING HEART-LUNG AND LUNG TRANSPLANTATION
241 ACUTE AND SUBACUTE NECROSIS OF LIVER; SPECIFIED INBORN ERRORS OF METABOLISM
263 CANCER OF LIVER OTHER THAN ANGIOSARCOMA
264 CONGESTIVE HEART FAILURE, CARDIOMYOPATHY, MALIGNANT ARRHYTHMIAS, AND COMPLEX CONGENITAL HEART DISEASE
307 CIRRHOSIS OF LIVER OR BILIARY TRACT; BUDD-CHIARI SYNDROME; HEPATIC VEIN THROMBOSIS; INTRAHEPATIC VASCULAR MALFORMATIONS; CAROLI'S DISEASE
310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA
563 ANGIOSARCOMA OF LIVER; INTRAHEPATIC BILE DUCT CARCINOMA

Solid Organ Transplants

HERC staff surveyed other state Medicaid programs regarding their coverage of solid organ transplants to determine best practices. The results of this query are shown in the table below. The major take away is that most state Medicaid programs require a transplant to be done at a Medicare certified center. Most states do not have additional guidelines other than that the transplant must be done at these centers. Some states, however, do have detailed coverage criteria. Such criteria might be general, such as "no active infection, no psychological impairment to complying with post-transplant treatment requirements, etc." Some states have very detailed criteria for some or all organs.

Other State Medicaid Transplant Policies

State	**No specific policy**	**Coverage limited to type of center**	**Specific general criteria**	**Specific organ criteria**
Rhode Island	X			
Washington		Center of Excellence		
Florida		Medicare Certified		
Oklahoma		Medicare Certified	Detailed	Detailed for each organ
Minnesota		Medicare Certified		General for certain organs, specific for others
California		Center of Excellence		Yes only for islet cell, kidney
Nevada			Very general Note: only cover kidney and liver transplants	
Missouri		Medicare Certified		
Texas		Organ Procurement and Transportation Network (OPTN) or UNOS certified	Detailed	Detailed for each organ

Solid Organ Transplants

HERC staff summary

The current transplant lines do not contain all possible diagnosis codes. To clarify that intent is for coverage when an organ has failed, staff recommends making more generic lines that include only diagnoses such as "end stage renal disease" or "liver failure." Regardless of the cause of the organ failure, transplant should be covered if the transplant center feels that it is the appropriate treatment for that particular patient's clinical situation.

General criteria regarding transplant coverage should be added as a guideline, including requiring the transplant to be done at a Medicare approved center, and general criteria about a patient's physical and psychosocial status. Specific criteria are proposed as outlined in other state policies or as already included in existing Prioritized List guidelines.

Note: there is no CPT code for corneal transplant and no line current contains a description of corneal transplant.

HERC staff recommendations:

1) Adopt a new guideline for all transplant line as shown below
    a. Based on other state Medicaid policies
    b. Note: the following general guidelines are included in the new rule being developed: Transplant "procedures must be furnished in a Medicare certified transplant facility; AND Treatment must be an approved standard of care and cannot be an experimental or investigational procedure"
2) Delete the previous transplant related guidelines as shown below
    a. Are now incorporated into the larger guideline
3) Make the following coding changes to line 83 DIABETES MELLITUS WITH END STAGE RENAL DISEASE Treatment: SIMULTANEOUS PANCREAS/KIDNEY (SPK) TRANSPLANT, PANCREAS AFTER KIDNEY (PAK) TRANSPLANT
    a. Delete ICD-10-CM T86.85X family (Complication of intestine transplant) (These codes will remain on other lines)
    b. Add ICD-10-CM Z94.0 (Kidney transplant status)
4) Make the following coding changes to line 99 END STAGE RENAL DISEASE Treatment Renal Transplant
    a. Delete **ALL** ICD-10-CM codes from this other **OTHER THAN**:
        i. N18.5 Chronic kidney disease, stage 5
        ii. N18.6 End stage renal disease
        iii. T86.1 Kidney transplant complication
        iv. Z48.22 Encounter for aftercare following kidney transplant
        v. Z52.4 Kidney donor
    b. The long list of diagnoses currently on this line does not include all possible causes of renal failure and are not needed as any cause of end stage renal disease should be eligible for renal transplant
5) Make the following coding changes to line 264 CONGESTIVE HEART FAILURE, CARDIOMYOPATHY, MALIGNANT ARRHYTHMIAS, AND COMPLEX CONGENITAL HEART DISEASE Treatment CARDIAC TRANSPLANT; HEART/KIDNEY TRANSPLANT
    a. Delete ICD-10-CM I49.01 (Ventricular fibrillation) and I49.02 (Ventricular flutter)

6) Make the following coding changes to line 307 CIRRHOSIS OF LIVER OR BILIARY TRACT; BUDD-CHIARI SYNDROME; HEPATIC VEIN THROMBOSIS; INTRAHEPATIC VASCULAR MALFORMATIONS; CAROLI'S DISEASE Treatment: LIVER TRANSPLANT, LIVER-KIDNEY TRANSPLANT
    a. Add ICD-10-CM K72.1X (chronic hepatic failure), K72.9X (hepatic failure, unspecified)
7) Consider combining all the liver transplant lines into a single line as a biennial review item
    a. Lines **162** BILIARY ATRESIA, **241** ACUTE AND SUBACUTE NECROSIS OF LIVER; SPECIFIED INBORN ERRORS OF METABOLISM, **263** CANCER OF LIVER OTHER THAN ANGIOSARCOMA; **307** CIRRHOSIS OF LIVER OR BILIARY TRACT; BUDD-CHIARI SYNDROME; HEPATIC VEIN THROMBOSIS; INTRAHEPATIC VASCULAR MALFORMATIONS; CAROLI'S DISEASE

GUIDELINE NOTE XXX SOLID ORGAN TRANSPLANTS

Lines 83,99,162,239,240,241,263,264,307,310,563

Solid organ transplants are included on these lines only when BOTH the general criteria AND the organ specific criteria below are met:

GENERAL TRANSPLANT CRITERIA

1) The patient must have irreversible end-stage organ disease or failure and must have medical therapy optimized; AND
2) The patient is a suitable surgical candidate for transplant surgery, indicated by ALL of the following:
    a. No significant uncontrolled co-morbidities such as:
        i. End-stage cardiac, renal, hepatic or other organ dysfunction unrelated to the primary indication for transplant
        ii. Uncontrolled HIV infection
        iii. Multiple organ compromise secondary to infection, malignancy, or condition with no known cure
        iv. Ongoing or recurrent active infections that are not effectively treated,
        v. Psychiatric instability severe enough to jeopardize adherence to medical regimen,
        vi. Active alcohol or illicit drug dependency; AND
    b. No tobacco smoking for at least 6 months unless the transplant is done on an emergent basis (other than for corneal transplants); AND
    c. Demonstrated compliance with medical treatments and ability to understand and comply with the post-transplant immunosuppressive regimen

HEART TRANSPLANT

Patients must have New York Heart Association (NYHA) Class III or IV cardiac disease (unless an infant with complex congenital heart disease) caused by one of the following:

1) Congenital heart disease
2) Cardiomyopathy
3) Myocarditis
4) Congestive heart failure

Solid Organ Transplants

The patient must have optimized medical therapy and no other medical or surgical procedure should offer realistic expectation of extension of life and functional improvement.

LUNG TRANSPLANT

Patients must have symptoms at rest directed related to chronic pulmonary disease and resultant severe functional limitations. The end stage pulmonary disease must be either due to:

1) Obstructive lung disease
2) Restrictive lung disease
3) Cystic fibrosis
4) Pulmonary hypertension

COMBINED HEART/LUNG TRANSPLANTATIONS

The patent must meet criteria for both heart and lung transplantation and neither a heart transplant or lung transplant alone would be expected to improve the individual's condition and chances of survival.

KIDNEY TRANSPLANT

The patient must have one of the following:

1) End-stage renal disease requiring hemodialysis or continuous ambulatory peritoneal dialysis; OR
2) End-stage renal disease, evidence by a creatinine clearance below 20 ml/min or development of symptoms of uremia; OR
3) Chronic renal failure with anticipated deterioration to end-stage renal disease requiring dialysis

HEART-KIDNEY TRANSPLANTS

Patients under consideration for heart/kidney transplant must qualify for each individual type of transplant with the exception of any exclusions due to heart and/or kidney disease.

LIVER TRANSPLANT

The patient must have irreversible, end stage, liver damage with no other available treatment options due to

1) cholestatic liver disease, OR
2) inborn errors of metabolism, OR
3) Hepatocellular injury, OR
4) Vascular disease (e.g. Budd-Chiari syndrome or veno-occlusive disease)
5) Primary hepatocellular carcinoma when the patient
    a. Is not a candidate for subtotal liver resection; AND
    b. There is no identifiable extra-hepatic spread of tumor

PANCREAS TRANSPLANTS

Pancreas transplant alone are not included on any transplant line. Simultaneous pancreas kidney transplant (SPT) is only included on this line for type I diabetes mellitus with end stage renal disease (E10.2). Pancreas after kidney transplant (PAK) is only included on this line for other type I diabetes mellitus with secondary diagnosis of Z94.0 (Kidney transplant status).

ISLET CELL AUTOTRANSPLANT

Islet cell autotransplant (TP IAT) is only included on line 250 when done with total pancreatectomy AND when the patient meets ALL of the following criteria:

A) Has acquired intractable chronic pancreatitis

B) Has intractable abdominal pain despite optimal medical therapy
C) Has not responded to more conservative surgery including endoscopic pancreatic decompression or in whom such surgery is not clinically indicated
D) Has not responded to nerve block procedures or in whom these interventions are not clinically indicated
E) Has been assessed by the multidisciplinary team and determined to have pain of an organic nature and are thought likely to achieve significant pain reduction from TP IAT
F) Is an appropriate candidate for major surgery
G) Is able to adhere to the complex medical management required following TP IAT
H) Does not have type 1 diabetes, known pancreatic cancer or any other condition that would prevent isolation of islet cells for autotransplant
I) Does not have a condition (e.g. portal vein thrombosis or significant parenchymal liver disease such as cirrhosis of the liver) which increases the risks associated with islet cell transplant
J) Does not have any other contraindications such as active alcohol abuse

INTESTINE TRANSPLANT

Intestine transplant is included on this line only for patients with failure of total parenteral nutrition (TPN) as indicated by one of the following, and no contraindications to transplant:

A) Impending or overt liver failure due to TPN, indicated by elevated serum bilirubin and/or liver enzymes, splenomegaly, thrombocytopenia, gastro-esophageal varices, coagulopathy, peristomal bleeding, or hepatic fibrosis/cirrhosis;
B) Thrombosis of ≥ 2 central veins, including jugular, subclavian, and femoral veins;
C) Two or more episodes of systemic sepsis due to line infection, per year, or one episode of septic shock, acute respiratory distress syndrome, and/or line related fungemia;
D) Frequent episodes of dehydration despite IV fluid supplementation;
E) Other complications leading to loss of vascular access

~~**GUIDELINE NOTE 42, PANCREAS/KIDNEY TRANSPLANTS**~~

~~*Line 83*~~

~~Simultaneous pancreas kidney transplant (SPT) is only included on this line for type I diabetes mellitus with end stage renal disease (E10.2). Pancreas after kidney transplant (PAK) is only included on this line for other type I diabetes mellitus with secondary diagnosis of Z94.0 (Kidney transplant status).~~

~~**GUIDELINE NOTE 70, HEART-KIDNEY TRANSPLANTS**~~

~~*Line 264*~~

~~Patients under consideration for heart/kidney transplant must qualify for each individual type of transplant under current DMAP administrative rules and transplant center criteria with the exception of any exclusions due to heart and/or kidney disease. Qualifying renal disease is limited to Stage V or VI.~~

~~**GUIDELINE NOTE 194, TOTAL PANCREATECTOMY WITH ISLET CELL AUTOTRANSPLANT**~~

~~*Line 250*~~

~~Total pancreatectomy with islet cell autotransplant (TP IAT) is only included on this line when the patient meets ALL of the following criteria:~~

~~K) Has acquired intractable chronic pancreatitis~~

L) Has intractable abdominal pain despite optimal medical therapy
M) Has not responded to more conservative surgery including endoscopic pancreatic decompression or in whom such surgery is not clinically indicated
N) Has not responded to nerve block procedures or in whom these interventions are not clinically indicated
O) Has been assessed by the multidisciplinary team and determined to have pain of an organic nature and are thought likely to achieve significant pain reduction from TP IAT
P) Is an appropriate candidate for major surgery
Q) Is able to adhere to the complex medical management required following TP IAT
R) Does not have type 1 diabetes, known pancreatic cancer or any other condition that would prevent isolation of islet cells for autotransplant
S) Does not have a condition (e.g. portal vein thrombosis or significant parenchymal liver disease such as cirrhosis of the liver) which increases the risks associated with islet cell transplant
T) Does not have any other contraindications such as active alcohol abuse

GUIDELINE NOTE 199, INTESTINE TRANSPLANT

Line 239

Intestine transplant is included on this line only for patients with failure of total parenteral nutrition (TPN) as indicated by one of the following, and no contraindications to transplant:

F) Impending or overt liver failure due to TPN, indicated by elevated serum bilirubin and/or liver enzymes, splenomegaly, thrombocytopenia, gastro-esophageal varices, coagulopathy, peristomal bleeding, or hepatic fibrosis/cirrhosis;
G) Thrombosis of ≥ 2 central veins, including jugular, subclavian, and femoral veins;
H) Two or more episodes of systemic sepsis due to line infection, per year, or one episode of septic shock, acute respiratory distress syndrome, and/or line related fungemia;
I) Frequent episodes of dehydration despite IV fluid supplementation;
J) Other complications leading to loss of vascular access

Appendix A
Current Solid Organ Transplant Lines and Guidelines

Line: 83

Condition: DIABETES MELLITUS WITH END STAGE RENAL DISEASE (See Guideline Note 42)
Treatment: SIMULTANEOUS PANCREAS/KIDNEY (SPK) TRANSPLANT, PANCREAS AFTER KIDNEY (PAK) TRANSPLANT
ICD-10: E10.21-E10.29,T86.10-T86.19,T86.850-T86.899,Z48.22,Z48.288
CPT: 48550-48556,50300-50365,76776,86825-86835,96156-96159,96164-96171,98966-98972, 99051,99060,99070,99078,99184,99203-99239,99281-99285,99291-99404,99411-99449, 99451,99452,99468-99472,99475-99480,99487-99491,99495-99498,99605-99607
HCPCS: G0068,G0071,G0088-G0090,G0248-G0250,G0396,G0397,G0406-G0408,G0425-G0427, G0463,G0466,G0467,G0490,G0508-G0511,G2011,G2012,G2211,G2212,G2214,G2251, G2252,S2065

Line: 99

Condition: END STAGE RENAL DISEASE
Treatment: RENAL TRANSPLANT
ICD-10: D30.9,D57.1,D59.3,D69.0,E08.21-E08.29,E09.21-E09.29,E10.21-E10.29,E11.21-E11.29, E13.21-E13.29,E75.21-E75.22,E75.240-E75.243,E75.248-E75.249,E75.3,E77.0,E77.8, E78.71-E78.72,I12.0,M30.0-M30.2,M30.8,M31.0,M31.31,M31.7,M32.14-M32.19,M35.04, M35.08-M35.0A,N00.8,N01.0-N01.A,N02.0-N02.A,N03.0-N03.A,N04.0-N04.A,N05.0-N05.A, N06.0-N06.A,N07.0-N07.A,N08,N11.0-N11.8,N14.0-N14.4,N15.0,N15.8-N15.9,N16,N17.0-N17.9,N18.5-N18.6,N26.1,N26.9,N28.0,Q60.0-Q60.2,Q60.4-Q60.6,Q61.19-Q61.5,Q62.0, Q62.10-Q62.39,Q79.4,Q79.51,Q87.2-Q87.3,Q87.5,Q87.81,Q87.89,Q89.8,T86.10-T86.19, Z48.22,Z52.4
CPT: 36825,36830,50300-50370,50547,52310,76776,86825-86835,96156-96159,96164-96171, 98966-98972,99051,99060,99070,99078,99184,99203-99239,99281-99285,99291-99404, 99411-99449,99451,99452,99468-99472,99475-99480,99487-99491,99495-99498,99605-99607
HCPCS: G0068,G0071,G0088-G0090,G0248-G0250,G0396,G0397,G0406-G0408,G0425-G0427, G0463,G0466,G0467,G0490,G0508-G0511,G2011,G2012,G2211,G2212,G2214,G2251, G2252

Line: 162

Condition: BILIARY ATRESIA
Treatment: LIVER TRANSPLANT
ICD-10: Q44.2-Q44.3,T86.40-T86.49,Z48.23,Z52.6
CPT: 47133-47147,86825-86835,96156-96159,96164-96171,98966-98972,99051,99060,99070, 99078,99184,99203-99239,99281-99285,99291-99404,99411-99449,99451,99452,99468-99472,99475-99480,99487-99491,99495-99498,99605-99607
HCPCS: G0068,G0071,G0088-G0090,G0248-G0250,G0396,G0397,G0406-G0408,G0425-G0427, G0463,G0466,G0467,G0490,G0508-G0511,G2011,G2012,G2211,G2212,G2214,G2251, G2252

Line: 239

Condition: SHORT BOWEL SYNDROME (See Guideline Note 199)
Treatment: INTESTINE AND INTESTINE/LIVER TRANSPLANT
ICD-10: K55.30-K55.33,K91.2,P77.1-P77.9,T86.850-T86.859,Z48.23,Z48.288
CPT: 44132,44135,44715-44721,47133-47147,82306,86825-86835,96156-96159,96164-96171,98966-98972,99051,99060,99070,99078,99184,99203-99239,99281-99285,99291-99404,99411-99449,99451,99452,99468-99472,99475-99480,99487-99491,99495-99498,99605-99607
HCPCS: G0068,G0071,G0088-G0090,G0248-G0250,G0396,G0397,G0406-G0408,G0425-G0427,G0463,G0466,G0467,G0490,G0508-G0511,G2011,G2012,G2211,G2212,G2214,G2251,G2252,S2053

Line: 240

Condition: CONDITIONS REQUIRING HEART-LUNG AND LUNG TRANSPLANTATION (See Guideline Notes 151 and 187)
Treatment: HEART-LUNG AND LUNG TRANSPLANT
ICD-10: D86.0,E84.0,E84.8,I27.0,I27.89,J41.8,J43.0-J43.8,J47.0-J47.9,J60,J61,J62.0-J62.8,J63.0-J63.6,J65,J66.0-J66.8,J67.0-J67.9,J70.1,J70.3-J70.4,J84.111-J84.117,J84.81-J84.83,J84.841-J84.89,T27.1XXA-T27.1XXD,T27.5XXA-T27.5XXD,T86.810-T86.818,Z48.21,Z48.24,Z48.280
CPT: 32850-32856,33930-33935,33946-33966,33969,33984-33989,81595,86825-86835,94625-94640,96156-96159,96164-96171,98966-98972,99051,99060,99070,99078,99184,99203-99239,99281-99285,99291-99404,99411-99449,99451,99452,99468-99472,99475-99480,99487-99491,99495-99498,99605-99607
HCPCS: G0068,G0071,G0088-G0090,G0237-G0239,G0248-G0250,G0396,G0397,G0406-G0408,G0424-G0427,G0463,G0466,G0467,G0490,G0508-G0511,G2011,G2012,G2211,G2212,G2214,G2251,G2252,S2060,S2061,S9473

Line: 241

Condition: ACUTE AND SUBACUTE NECROSIS OF LIVER; SPECIFIED INBORN ERRORS OF METABOLISM (E.G., MAPLE SYRUP URINE DISEASE, TYROSINEMIA)
Treatment: LIVER TRANSPLANT
ICD-10: D81.810,D84.1,E70.20-E70.29,E70.330-E70.331,E70.5,E70.81-E70.9,E71.0,E71.110-E71.2,E72.10-E72.29,E72.52-E72.53,E72.81,E74.00-E74.09,E80.5,E83.00-E83.10,E83.110-E83.19,K72.00-K72.01,K73.1-K73.8,K76.2,T86.40-T86.49,Z48.23,Z52.6
CPT: 47133-47147,86825-86835,96156-96159,96164-96171,97802-97804,98966-98972,99051,99060,99070,99078,99184,99203-99239,99281-99285,99291-99404,99411-99449,99451,99452,99468-99472,99475-99480,99487-99491,99495-99498,99605-99607
HCPCS: G0068,G0071,G0088-G0090,G0248-G0250,G0396,G0397,G0406-G0408,G0425-G0427,G0463,G0466,G0467,G0490,G0508-G0511,G2011,G2012,G2211,G2212,G2214,G2251,G2252

Line: **263**
Condition: CANCER OF LIVER OTHER THAN ANGIOSARCOMA
Treatment: LIVER TRANSPLANT
ICD-10: C22.0,C22.2,C22.4-C22.8,T86.40-T86.49,Z48.23,Z51.11,Z52.6
CPT: 47133-47147,86825-86835,98966-98972,99051,99060,99070,99078,99184,99203-99239,99281-99285,99291-99404,99411-99416,99421-99449,99451,99452,99468-99472,99475-99480,99487-99491,99495-99498,99605-99607
HCPCS: G0068,G0071,G0088-G0090,G0248-G0250,G0396,G0397,G0406-G0408,G0425-G0427,G0463,G0466,G0467,G0490,G0508-G0511,G2011,G2012,G2211,G2212,G2251,G2252

Line: **264**
Condition: CONGESTIVE HEART FAILURE, CARDIOMYOPATHY, MALIGNANT ARRHYTHMIAS, AND COMPLEX CONGENITAL HEART DISEASE (See Guideline Notes 18,70 and 151)
Treatment: CARDIAC TRANSPLANT; HEART/KIDNEY TRANSPLANT
ICD-10: I13.11-I13.2,I25.110,I25.5,I40.0-I40.9,I42.0-I42.8,I47.2,I49.01-I49.02,I50.1,I50.20-I50.43,N18.5-N18.6,Q20.1-Q20.5,Q20.8,Q23.4,T86.21-T86.23,T86.290-T86.298,T86.31-T86.39,Z45.09,Z48.21,Z48.280-Z48.288
CPT: 33620,33621,33741,33940-33966,33969,33975-33989,33992,33993,33997,50300-50370,50547,75573,76776,81595,86825-86835,92960-92971,92978-92998,93593-93598,93750,93797,93798,96156-96159,96164-96171,98966-98972,99051,99060,99070,99078,99091,99184,99203-99239,99281-99285,99291-99404,99411-99449,99451-99453,99457,99458,99468-99480,99487-99491,99495-99498,99605-99607
HCPCS: G0068,G0071,G0088-G0090,G0157-G0161,G0248-G0250,G0396,G0397,G0406-G0408,G0422,G0423,G0425-G0427,G0463,G0466,G0467,G0490,G0508-G0511,G2011,G2012,G2211,G2212,G2214,G2251,G2252

Line: **307**
Condition: CIRRHOSIS OF LIVER OR BILIARY TRACT; BUDD-CHIARI SYNDROME; HEPATIC VEIN THROMBOSIS; INTRAHEPATIC VASCULAR MALFORMATIONS; CAROLI'S DISEASE
Treatment: LIVER TRANSPLANT, LIVER-KIDNEY TRANSPLANT
ICD-10: I82.0,K65.2,K70.2,K70.30-K70.31,K74.02,K74.3-K74.5,K74.60-K74.69,K76.81,P59.1,P59.20-P59.29,P76.8-P76.9,P78.1,P78.81,P78.84,Q44.6,T86.40-T86.49,Z48.22-Z48.23,Z48.288,Z52.6
CPT: 47133-47147,50300,50323-50365,76776,82306,86825-86835,96156-96159,96164-96171,98966-98972,99051,99060,99070,99078,99184,99203-99239,99281-99285,99291-99404,99411-99449,99451,99452,99468-99472,99475-99480,99487-99491,99495-99498,99605-99607
HCPCS: G0068,G0071,G0088-G0090,G0248-G0250,G0396,G0397,G0406-G0408,G0425-G0427,G0463,G0466,G0467,G0490,G0508-G0511,G2011,G2012,G2211,G2212,G2214,G2251,G2252

Line: 310
Condition: CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA (See Guideline Note 168)
Treatment: KERATOPLASTY
ICD-10: E50.4,H17.00-H17.13,H17.811-H17.89,H18.011-H18.13,H18.221-H18.229,H18.40,H18.411-H18.799,Q13.3-Q13.4
CPT: 65286,65400,65435-65450,65710-65757,65772-65785,65920,66250,66825,66985,66986,66990,68110-68135,68371,76514,92002-92014,92018-92060,92072,92100,92132,92134,92136,92201,92202,92230-92270,92283-92310,92313-92342,92370,98966-98972,99051,99060,99070,99078,99184,99203-99239,99281-99285,99291-99404,99411-99449,99451,99452,99468-99472,99475-99480,99487-99491,99495-99498,99605-99607
HCPCS: G0068,G0071,G0088-G0090,G0248-G0250,G0396,G0397,G0406-G0408,G0425-G0427,G0463,G0466,G0467,G0490,G0508-G0511,G2011,G2012,G2211,G2212,G2214,G2251,G2252

Line: 563
Condition: ANGIOSARCOMA OF LIVER; INTRAHEPATIC BILE DUCT CARCINOMA
Treatment: LIVER TRANSPLANT
ICD-10: C22.1,C22.3,T86.40-T86.49,Z48.23,Z51.11,Z52.6
CPT: 47133-47147,86825-86835,98966-98972,99051,99060,99070,99078,99184,99203-99239,99281-99285,99291-99404,99411-99449,99451,99452,99468-99472,99475-99480,99487-99491,99495-99498,99605-99607
HCPCS: G0068,G0071,G0088-G0090,G0248-G0250,G0396,G0397,G0406-G0408,G0425-G0427,G0463,G0466,G0467,G0490,G0508-G0511,G2011,G2012,G2211,G2212,G2214,G2251,G2252

GUIDELINE NOTE 42, PANCREAS/KIDNEY TRANSPLANTS

Line 83

Simultaneous pancreas kidney transplant (SPT) is only included on this line for type I diabetes mellitus with end stage renal disease (E10.2). Pancreas after kidney transplant (PAK) is only included on this line for other type I diabetes mellitus with secondary diagnosis of Z94.0 (Kidney transplant status).

GUIDELINE NOTE 70, HEART-KIDNEY TRANSPLANTS

Line 264

Patients under consideration for heart/kidney transplant must qualify for each individual type of transplant under current DMAP administrative rules and transplant center criteria with the exception of any exclusions due to heart and/or kidney disease. Qualifying renal disease is limited to Stage V or VI.

GUIDELINE NOTE 194, TOTAL PANCREATECTOMY WITH ISLET CELL AUTOTRANSPLANT

Line 250

Total pancreatectomy with islet cell autotransplant (TP IAT) is only included on this line when the patient meets ALL of the following criteria:

U) Has acquired intractable chronic pancreatitis
V) Has intractable abdominal pain despite optimal medical therapy
W) Has not responded to more conservative surgery including endoscopic pancreatic decompression or in whom such surgery is not clinically indicated

X) Has not responded to nerve block procedures or in whom these interventions are not clinically indicated
Y) Has been assessed by the multidisciplinary team and determined to have pain of an organic nature and are thought likely to achieve significant pain reduction from TP IAT
Z) Is an appropriate candidate for major surgery
AA) Is able to adhere to the complex medical management required following TP IAT
BB) Does not have type 1 diabetes, known pancreatic cancer or any other condition that would prevent isolation of islet cells for autotransplant
CC) Does not have a condition (e.g. portal vein thrombosis or significant parenchymal liver disease such as cirrhosis of the liver) which increases the risks associated with islet cell transplant
DD) Does not have any other contraindications such as active alcohol abuse

GUIDELINE NOTE 199, INTESTINE TRANSPLANT

Line 239

Intestine transplant is included on this line only for patients with failure of total parenteral nutrition (TPN) as indicated by one of the following, and no contraindications to transplant:

K) Impending or overt liver failure due to TPN, indicated by elevated serum bilirubin and/or liver enzymes, splenomegaly, thrombocytopenia, gastro-esophageal varices, coagulopathy, peristomal bleeding, or hepatic fibrosis/cirrhosis;
L) Thrombosis of ≥ 2 central veins, including jugular, subclavian, and femoral veins;
M) Two or more episodes of systemic sepsis due to line infection, per year, or one episode of septic shock, acute respiratory distress syndrome, and/or line related fungemia;
N) Frequent episodes of dehydration despite IV fluid supplementation;
O) Other complications leading to loss of vascular access

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 482, 488, and 498

Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 482, 488, and 498

[CMS–3835–F]

RIN 0938–AH17

Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule establishes, for the first time, Medicare conditions of participation for heart, heart-lung, intestine, kidney, liver, lung, and pancreas transplant centers. This rule sets forth clear expectations for safe, high quality transplant service delivery in Medicare-participating facilities. In addition, in this rule we respond to public comments on the proposed rule.

EFFECTIVE DATES: These regulations are effective on June 28, 2007.

FOR FURTHER INFORMATION CONTACT: Eva Fung, (410) 786–7539. Marcia Newton, (410) 786–5265. Diane Corning, (410) 786–8486. Jeannie Miller, (410) 786–3164. Rachael Weinstein, (410) 786–6775.

SUPPLEMENTARY INFORMATION:

I. Background

A. Key Statutory Provisions

Section 1102 of the Social Security Act (the Act) authorizes the Secretary to publish rules and regulations ''necessary for the efficient administration of the functions'' with which the Secretary is charged under the Act. Section 1871(a) of the Act authorizes the Secretary to ''prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title.''

Section 1864 of the Act authorizes the use of State agencies to determine providers' compliance with Medicare conditions of participation (CoPs). Responsibilities of the States in ensuring compliance with the CoPs are set forth in regulations at 42 CFR part 488, Survey, Certification, and Enforcement Procedures. Under section 1865 of the Act and § 488.5 of the regulations, hospitals that are accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the American Osteopathic Association (AOA) are not routinely surveyed by State agency surveyors for compliance with the conditions, but are deemed to meet most of the requirements in the hospital CoPs based on their accreditation. JCAHO, AOA, and other national accreditation programs with deeming authority under § 488.6 of the regulations must meet requirements that are at least as stringent as the Medicare CoPs. (See Part 488, Survey and Certification Procedures.) An accreditation organization must apply for and receive approval of deeming authority from CMS.

Section 1865(b)(1) of the Act states that providers of certain services listed in section 1881(b) of the Act cannot be deemed by a national accreditation body to meet the Medicare conditions of participation. Kidney transplant centers are entities listed in 1881(b); thus, they cannot be deemed to be accredited.

Section 1881(b)(1) of the Act contains specific authority for prescribing the health and safety requirements for facilities, including renal transplant centers, that furnish end stage renal disease (ESRD) care to beneficiaries.

B. Past Medicare Policy Regarding Transplantation

Until now, kidney transplant centers have participated in Medicare by meeting requirements set forth at 42 CFR Part 405, subpart U, ''Conditions for Coverage of Suppliers of End Stage Renal Disease (ESRD) Services.'' These requirements address issues such as compliance with applicable Federal, State, and local laws and regulations; governing body; patient care plans; patients' rights; medical records; and the physical environment. In addition, the ESRD conditions for coverage (CfCs) delineate minimum utilization rates, requirements for the director of transplantation, and minimum service requirements. (See 405.2170 and 405.2171.) Likewise, we have regulated extra-renal transplant centers under various national coverage decisions (NCDs) published beginning in 1987. The NCDs have been based on the ''reasonable and necessary'' provision of the Medicare statute (section 1862(a)(1)(A) of the Act). Generally, under section 1862(a)(1)(A), Medicare does not pay for any item or service unless it is medically reasonable and necessary. The NCDs provide that transplantation of extra-renal organs will be considered reasonable and necessary if performed in a center that meets the criteria specified in the applicable NCD.

C. Our Efforts To Improve Oversight of Transplant Centers

In the preamble of the proposed transplant center rule published February 4, 2005 (70 FR 6140), we discussed our efforts that are underway to improve organ donation and transplantation services, including the Secretary's Gift of Life Initiative. Publication of the proposed rule for new CoPs for transplant centers was the first step in moving toward a stronger oversight process. In February 2004, the Office of the Inspector General (OIG) published a report titled ''Medicare-approved Heart Transplant Centers'' (OEI–01–02–00520), and outlined three recommendations for CMS oversight of heart transplant centers: (1) CMS should expedite the development of continuing criteria for volume and survival rate performance and for periodic re-certification; (2) CMS should develop guidelines and procedures for taking actions against centers that do not meet Medicare criteria for volume and survival rate; and (3) CMS should take immediate steps to improve its ability to maintain accurate and timely data on center performance. All of the OIG's recommendations were incorporated into the rule.

Through this final rule, we are codifying requirements for approval and re-approval of transplant centers as CoPs and placing Medicare-approved transplant centers under the survey and certification enforcement process used for all other providers and suppliers of Medicare services.

Since publication of the proposed rule, we have identified quality and service issues that some transplant centers are experiencing. For example, in 2005, we investigated and cited a hospital whose liver transplant center was accused of turning down a large number of organs offered for the patients on its waiting list. As a result, the hospital closed its liver transplant center. In addition, the Government Accountability Office (GAO) is currently reviewing the Department's oversight of the transplantation system in the United States.

Our current oversight of transplant centers relies on self-reporting of significant changes within a transplant center, as well as beneficiary complaints that may lead to a review or survey of a transplant center. The transplant center NCDs do not delineate explicit criteria for de-certifying of organ transplant programs. In this final rule, we are responding to public comments on the proposed rule and recommendations for improvement to this system by setting forth explicit

expectations for outcomes, and high quality transplantation services.

We are codifying the requirements for the approval and re-approval of transplant centers as an option under part 482, subpart E, for hospitals that choose to perform transplants. This final rule applies to hospitals with heart, heart-lung, intestine, kidney, liver, lung, and pancreas transplant centers. For purposes of this final rule, heart-lung transplant centers are those centers that are located in a hospital with an existing Medicare-approved heart transplant center and an existing Medicare-approved lung center that performs combined heart-lung transplants. Intestine centers are those Medicare-approved liver transplant centers that perform intestine transplants, combined liver-intestine transplants, and multivisceral transplants. Pancreas centers are those Medicare-approved kidney transplant centers that perform pancreas transplants, alone or subsequent to a kidney transplant, and that also perform kidney-pancreas transplants.

II. Provisions of the Proposed Rule and Response to Comments on the February 4, 2005 Proposed Rule

In the February 4, 2005 **Federal Register** (70 FR 6140), we published the proposed rule entitled, ''Hospital Conditions of Participation: Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplants'' and provided for a 60-day comment period. On March 25, 2005, we published a notice in the **Federal Register** (70 FR 15264) extending the comment period for an additional 60 days, until June 6, 2005, to allow sufficient time for the public to provide comments on the large number of proposed new requirements.

The proposed rule set forth new hospital CoPs for the approval and re-approval of transplant centers at 42 CFR part 482, subpart E. Additionally, following publication of the proposed rule, we conducted an external, independent peer review of several of the technical aspects associated with the proposed outcome measures and options. We contacted five scientists, of which three sent us detailed comments to address the technical questions that we raised. One scientist declined to provide detailed comments but said his views were reflected by the comments provided by the American Society of Transplant Surgeons/American Transplantation Society (ASTS/ATS). Comments provided by the ASTS/ATS partially addressed these technical issues, as well as more general issues of concern to the society. These peer reviews were received during the public comment period. Below we respond to the comments of the peer reviewers, in addition to the public comments received during the comment period.

We received a total of 91 comments: 48 from individual transplant centers; 10 from professional associations representing those who work in the field of transplantation (including physicians, surgeons, dietitians, nurses, social workers, transplant coordinators, hospitals), 2 from organizations that support transplantation, (that is, the National Kidney Foundation and National Liver Foundation); 9 from individual social workers; 6 from individual transplant coordinators; 5 from individual organ procurement organizations; and 11 from various sources (including the Scientific Registry of Transplant Recipients, United Network for Organ Sharing, the Secretary's Advisory Committee on Organ Transplantation, the New York State Department of Health, the Joint Commission on Accreditation of Healthcare Organizations, individual physicians, a histocompatability laboratory, a living donor, and a dialysis facility). The comments ranged from general support or opposition to the proposed conditions of participation to very specific questions or comments regarding the proposed criteria. Note that comments made by peer reviewers are identified specifically as peer review comments. All other comments were made by the public.

Brief summaries of each proposed provision, a summary of the public comments we received (with the exception of specific comments on the paperwork burden or the economic impact analysis), and our responses to the comments are set forth below. Comments related to the paperwork burden and the impact analysis are addressed in the Collection of Information and Impact Analysis Sections in this preamble.

General Comments

Comment: Many commenters supported and commended our efforts to update Medicare approval and re-approval requirements for transplant centers. Some commenters indicated they were impressed by our recognition of the highly complex issues faced by transplant recipients and living donors. Other commenters stated that the rationales provided in the February 4, 2005 proposed rule were based on sound medical and transplant practices. Some commenters stated that this rule may help to decrease organ wastage and graft failure, which would reduce the need for kidney dialysis services and re-transplantation of failed organs.

Some of the professional associations and three peer reviewers supported our efforts to update transplantation standards for Medicare-approved centers, codify standards for extra-renal organ transplants, and improve care for Medicare beneficiaries and living donors. One peer reviewer was pleased with the comprehensiveness of the proposed rule, which the peer reviewer said builds upon the work of the Organ Procurement and Transplantation Network (OPTN), the Scientific Registry of Transplant Recipients (SRTR), and the Health Resources and Services Administration (HRSA). Another peer reviewer supported the re-approval process and stated that a mechanism to re-approve transplant centers is essential.

Response: We thank the commenters and peer reviewers for their assistance in developing this final rule. We are committed to ensuring that Medicare-approved transplant centers consistently maintain the expertise and resources necessary to provide high quality transplantation services to patients.

Comment: A few commenters stated that the proposed rule was too prescriptive and expressed concerns that implementation of the rule would bring extra burden to transplant centers, especially kidney transplant centers, in terms of cost and nursing hours. One commenter suggested a more general approach as opposed to using prescriptive language. One commenter inquired about the source of funding for the extra expenses generated by this rule.

Response: One of our goals in publishing new CoPs for transplant centers is to provide flexibility for transplant centers within the framework of our regulatory authority. As stated in the proposed rule, we have set forth requirements that we believe are absolutely necessary to ensure quality care and protect the health and safety of patients. All of the CoPs are specifically transplant-oriented, and we believe that nearly all requirements in this final rule clarify or strengthen normal business practices for most transplant centers. Centers that have not incorporated the requirements in this final rule into their normal business practices will need to assess their transplantation practices and improve their performance. We believe this rule will strengthen accountability of transplant centers, and we expect centers to maintain compliance with the requirements in this final rule and continuously strive to improve quality of care and patient and

living donor safety in their pursuit of optimal outcomes.

We believe this rule will neither increase nursing workloads nor create significant burdens for centers, including kidney centers. We estimate that on average, the cost for each currently-approved Medicare transplant center to comply will be less than $56,000 in the first full year following the effective date of the final rule and less than $21,000 in subsequent years.

Comment: A peer reviewer expressed concern that the level of detail in the proposed rule may hamper the Agency's ability to make needed modifications in the future.

Response: We have included only those requirements that we believe are absolutely essential for ensuring quality care and protecting the health and safety of Medicare beneficiaries and living donors. From an oversight perspective, we must be specific in our expectations so that providers clearly understand the requirements for Medicare participation.

We will continue to stay abreast of the latest advances in transplantation. If hospitals significantly change how they provide transplant patient care or the SRTR changes its outcome measure methodology, we will review and revise the final rule as necessary.

Comment: One commenter stated that the OPTN oversight process and the CoPs would create inconsistent parallels for review of transplant center performance. Another commenter was concerned that the OPTN and the proposed CMS review processes were duplicative or inconsistent in some areas. The commenter believed that the OPTN oversight and compliance with the Medicare CoPs should be consistent and work in tandem.

Response: Our intent is that OPTN policies and the requirements in this final rule will complement but not duplicate each other. Nevertheless, in some instances, we have incorporated OPTN policies into our requirements so that they are enforceable under Medicare. Below is a crosswalk chart that shows overlap and differences between OPTN policies and CMS regulations:

CROSSWALK OF TRANSPLANT CENTER FINAL RULE, PART 121, & OPTN POLICIES AND BYLAWS

CMS requirements	42 CFR Part 121, OPTN policies, and bylaws for transplant centers	Comments
Main focuses of CMS requirements. • Regulatory oversight of transplant centers. • Patient care & transplant services furnished to beneficiaries. • Relationship with transplant centers based on Provider Agreement & Medicare reimbursement. • Medicare approval & re-approval based on compliance with Conditions of participation (CoPs). • Provider responsibilities.	Part 121 sets forth the governing structure of the OPTN and sets standards for availability of organ transplantation data. Part 121 lays out requirements for transplant program in hospitals at §§ 121.9 and 121.11(b)(1)(C) (defined as OMB-approved OPTN forms). Main focuses of Part 121. • Govern the operation of the OPTN which is under contract with HRSA. • Require OPTN to develop policies for its members. However, as of today, with the exception of ''data submission requirements'', none of the OPTN polices have been enforceable because they have not been approved and published by the Secretary.	Main focuses of OPTN policies/Bylaws. • Organ allocation. • Credential of transplant surgeons/physicians. • Relationship with transplant hospital members is collegial with the goal to help them to improve performance. • OPTN Membership application reviewed by peer reviewers. • Member obligations. *Additional requirements for non-Medicare approved transplant programs.
§ 482.68 Special Requirements for transplant centers. In order to be granted approval from CMS to provide transplant services, a transplant center must: • Be located within a hospital that has a Medicare provider agreement. • Meet the CoPs of this final rule. • Meet all hospital CoPs.	Compliance with Part 121 ..... OPTN membership requirements.	• This rule now makes the data submission requirements of OPTN a Condition of Participation. • Transplant centers must comply with CoPs to be reimbursed.
§ 482.70 Definitions. CMS has specific definitions for certain types of centers.	Generic definitions in part 121	No comparable OPTN definitions.
§ 482.72 Condition of participation: OPTN membership. A transplant center must be located in a transplant hospital that is a member of and abides by the approved rules and requirements of the OPTN established and operated in accordance with § 372 of the Public Health Service (PHS) Act (42 U.S.C. section 274).	§ 121.9 Designated transplant program requirements. • (a) To receive organs for transplantation, a transplant program must be in a hospital that is a member of the OPTN.	
§ 482.74 Condition of participation: Notification to CMS. A transplant center must notify CMS immediately of any significant changes related to the center's transplant program or changes that would alter elements in the approval/re-approval application: • A change in key staff members of the transplant team. • A decrease in the center's volume or survival rates.	OPTN Bylaw Appendix B–3 ..... OPTN member programs must notify OPTN immediately when a key person plans to leave.	CMS adopts the OPTN bylaw and adds more requirements.

CROSSWALK OF TRANSPLANT CENTER FINAL RULE, PART 121, & OPTN POLICIES AND BYLAWS—Continued

CMS requirements	42 CFR Part 121, OPTN policies, and bylaws for transplant centers	Comments
• Termination of an agreement between the hospital in which the transplant center is located and an OPO for the recovery and receipt of organs. • Inactivation of the transplant center.		
§ 482.76 Condition of participation: Pediatric Hospitals. • With the exceptions of heart centers, pediatric centers that wish to provide transplantation services to both adult and pediatric transplants must meet all requirements (except for clinical experience) in this rule and request separate Medical approval. • A center that mostly performs adult transplants cannot be approved to perform pediatric transplants if they lose their approval to perform adult transplants. • A center that mostly performs pediatric transplants cannot be approved to perform adult transplants if they lose their approval to perform pediatric transplants. • Heart centers that want to obtain Medicare approval for pediatric transplants have the option to be approved under the criteria listed under OBRA 1987.	.....	No specific OPTN policy/bylaw for pediatric transplant programs.
§ 482.80 Condition of participation: Data submission, clinical experience, and outcome requirements for *INITIAL APPROVAL* of transplant centers.	§ 121.11(b)(2) Reporting requirements. Member transplant hospitals must submit to the Secretary information as the Secretary prescribes (OPTN forms).	By using the publicly available SRTR data for outcome measures, CMS's outcome complements Part 121.
(a) Standard: Data submission. No later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of required data on all transplants (deceased and living donor) it has performed.	§ 121.11(b)(1)(C) • The OPTN & the SRTR shall provide to the Secretary any data that the Secretary requests. • Make available to the public timely & accurate program-specific information on the performance of transplant programs. OPTN Policy 7.8 Data Submission Requirements. • Each transplant center must collect & submit 95% of expected forms complete within 3 months of the due date and 100% of expected forms complete within 6 months of the due date.	CMS adopts the OPTN policy for the most part.
(b) Standard: Clinical experience. We require an annual volume for the following types of transplant centers: • Heart, intestine, liver & lung transplant centers—10 transplants. • Kidney transplant centers—at least 3 transplants. • No annual volume requirement for heart-lung, and pancreas centers, and centers that primarily perform pediatric transplants.	No annual volume required by the OPTN. However, it has definitions for ''functionally inactive'' centers: • No transplants performed in 3 months in the case of kidney, liver, & heart transplant programs. • No transplants performed in 6 months in the case of pancreas & lung programs.	CMS requirements are straighter than OPTN policy for the purpose of monitoring inactivity of centers.

CROSSWALK OF TRANSPLANT CENTER FINAL RULE, PART 121, & OPTN POLICIES AND BYLAWS—Continued

CMS requirements	42 CFR Part 121, OPTN policies, and bylaws for transplant centers	Comments
(c) Standard: Outcome measures ..... • We will review outcomes for all transplants performed at a center, including outcomes for living donor transplants, if applicable. Except for lung transplants, CMS will review adult and pediatric outcomes separately when a center requests Medicare approval to perform pediatric transplants. • A center's (risk-adjusted) expected 1-year patient survival and 1-year graft survival will be compared to its observed 1-year patient survival and 1-year graft survival, based on the following non-compliance thresholds:. • O − E >3. • O/E >1.5. • 1-sided p <0.05.	OPTN Bylaw Appendix B Attachment Survival Rates. • While the precise numerical criteria may be selected by the Membership & Professional service Committee, the initial criteria employed to identify programs with low patient/graft survival rates will include the following findings: • O − E >3. • O/E >1.5. • 1-sided p <0.05.	CMS adopts the OPTN bylaws to the extent that the outcome measure standards and the OPTN policies for survival rate criteria & outcome methodology are essentially the same in the assessment of a center's outcomes. However, OPTN uses the survival outcomes as flags for further investigation while CMS uses them as criteria to make approval & re-approval determinations. Compliance with the OPTN's survival rate criteria is not required for initial approval of a new transplant program as an OPTN member. The OPTN grants conditional approval to new transplant programs, which gives the new transplant program 3 years to comply with the OPTN requirements.
(d) Exceptions. No outcome requirements for: • Heart-lung transplant centers. • Intestinal transplant centers. • Pancreas transplant centers.		
§ 482.82 Condition of participation: Data submission, clinical experience, and outcome requirements for *RE-APPROVAL* of transplant centers.		
(a) Standard: Data submission. No later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN 95 percent of the required data submissions on all transplants (deceased and living donor) it has performed over the 3-year approval period.	See Initial Approval	See Initial Approval.
(b) Standard: Clinical experience. We require an annual volume for the following types of transplant centers: • Heart, intestine, kidney, liver & lung transplant centers—10 transplants. • No annual volume requirement for heart-lung, and pancreas centers, and centers that primarily perform pediatric transplants.	See Initial Approval	See Initial Approval.
(c) Standard: Outcome measures ..... • We will review outcomes for all transplants performed at a center, including outcomes for living donor transplants, if applicable. Except for lung transplants, CMS will review adult and pediatric outcomes separately when a center requests Medicare approval to perform pediatric transplants. • A center's (risk-adjusted) expected 1-year patient survival and 1-year graft survival will be compared to its observed 1-year patient survival and 1-year graft survival, based on the following non-compliance thresholds: • O − E >3. • O/E >1.5. • 1-sided p <0.05.	See Initial Approval	See Initial Approval.
(d) Exceptions. No outcome requirements for: • Heart-lung transplant centers. • Intestinal transplant centers. • Pancreas transplant centers.		
§ 482.90 Condition of participation: Patient and living donor selection.	§ 121.8 Allocation of Organs	CMS requirements complement OPTN policies.
(a) Standard: Patient selection. Patient selection criteria must: • Assure fair and non-discriminatory distribution of organs. • Include a psychosocial evaluation.	The OPTN has wait list policies for the purpose of organ allocation.	

CROSSWALK OF TRANSPLANT CENTER FINAL RULE, PART 121, & OPTN POLICIES AND BYLAWS—Continued

CMS requirements	42 CFR Part 121, OPTN policies, and bylaws for transplant centers	Comments
• Include documentation in the patient's medical record that the candidate's blood type has been determined on at least two separate occasions. • Include documentation in the patient's medical record of the patient selection criteria used.		
(b) Standard: Living donor selection. The living donor selection criteria must be consistent with the general principles of medical ethics. Transplant centers must: • Ensure that a prospective living donor receives a medical & Psychosocial evaluation prior to donation. • Document in the living donor's medical records the living donor's suitability for donation. • Document that the living donor has given informed consent, as required.		No comparable OPTN policy/bylaw.
§ 482.92 Condition of participation: Organ recovery and receipt. • Written protocols for—deceased organ recovery, organ receipt, and living donor transplantation to validate donor-recipient matching of blood types and other vital information. • The transplanting surgeon at the transplant center responsible for ensuring medical suitability of donor organs for transplantation into the intended recipient.		
(a) Standard: Organ recovery. When an intended transplant recipient is known, the transplant center's organ recovery team must review and compare donor-data with the recipient blood type and other vital information before organ recovery takes place.	Policy 3.1 Organ Distribution: Definitions. 3.1.2 Transplant Center—The transplanting surgeon is responsible for ensuring medical suitability of donor organ for transplantation into the potential recipient, including compatibility of donor and candidate by ABO blood type.	CMS requirements complement OPTN policies.
(b) Standard: Organ receipt. • When an organ arrives at the center, the transplanting surgeon and at least one licensed health care professional must verify that the donor's blood type and other vital information is compatible with transplantation of the intended recipient prior to transplantation.	Policy 3.1 Organ Distribution: Definitions. 3.1.2 Transplant Center—Upon receipt of an organ, prior to implantation, the transplant center is responsible for verifying the recorded donor ABO with the recorded ABO of the intended recipient.	CMS requirements complement OPTN policies.
(c) Standard: Living donor transplantation. • If a center performs living donor transplants, the transplanting surgeon and at least one licensed health care professional at the transplant center must verify that the donor's blood type and other vital information is compatible with transplantation of the intended recipient immediately before the removal of the donor organ(s) and, if applicable, prior to the removal of the recipient's organ(s).	.....	No comparable OPTN policy/bylaw.
§ 482.94 Condition of participation: Patient and living donor management. • Transplant center must have written patient management policies and patient care planning for the pre-transplant, transplant, and discharge phases of transplantation. • Center must have written donor management policies for the donor evaluation, donation, and discharge phases of living organ donation if it performs living donor transplants.	.....	No comparable OPTN policy/bylaw.
(a) Standard: Patient and living donor care. ..... Each transplant patient and/or living donor is under the care of a multidisciplinary patient care team coordinated by a physician throughout transplantation or donation.	.....	No comparable OPTN policy/bylaw.

CROSSWALK OF TRANSPLANT CENTER FINAL RULE, PART 121, & OPTN POLICIES AND BYLAWS—Continued

CMS requirements	42 CFR Part 121, OPTN policies, and bylaws for transplant centers	Comments
(b) Standard: Waitlist management. Transplant centers must keep their waitlists up to date, including: • Updating waitlist patients' clinical information on an ongoing basis. • Removing patients from the center's waitlist if a patient receives a transplant or dies, or if there is any other reason why the patient should no longer be on a center's waitlist. • Notifying the OPTN no later than 24 hours after a patient's removal from the center's waitlist.	OPTN Policies 3.2.3.1, 3.6.6 ..... • Require transplant centers to immediately remove transplant candidates that have received a transplant from a deceased donor, or have died while awaiting a transplant, from the center's waitlist and from the UNOS Patient Waiting List and to notify UNOS within 24 hours of such removal.	CMS Requirements complement OPTN policies.
(c) Standard: Patient records. Transplant centers must maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a center's waitlist and who is admitted for organ transplantation. This includes notification to patient (and patient's usual dialysis facility if patient is a kidney patient) of: • Patient's placement on the center's waitlist; the center's decision not to place the patient on its waitlist; or the center's inability to make a determination regarding the patient's placement on its waitlist because further clinical testing or documentation is needed. • Removal from waitlist for reasons other than transplantation or death within 10 days. • Patient records must contain documentation of: • Multidisciplinary patient care planning during the pre-transplant period. • Multidisciplinary discharge planning for post-transplant care.	OPTN Bylaw Appendix B ..... II.C.10 Transplant Programs: Patient Notification Transplant programs must notify patients in writing: (i) within ten business days (a) of the patient's being placed on the UNOS Patient Waiting List including the date the patient was listed, or (b) of completion of the patient's evaluation as a candidate for transplantation, that the evaluation has been completed and that the patient will not be placed on the UNOS Patient Waiting List at this time, whichever is applicable; and (ii) within ten business days of removal from the UNOS Patient Waiting List as a transplant candidate for reasons other than transplantation or death that the patient has been removed from the Waiting List. The transplant program must maintain.	CMS adopts OPTN bylaw for the most part.
(d) Standard: Social services. The transplant center must make available social services, furnished by qualified social workers, to transplant patients, living donors, and their families. Definitions for a qualified social worker included.	§ 121.9(a) Designated Transplant Program Requirements OPTN Bylaw Appendix B, Attachment I, III.C.15 Transplant Programs: Social Support—Psychiatric and social support services must be available in transplant programs approved under 121.9(a)(2).	The OPTN bylaw does not define qualification of a qualified social worker. CMS requirement complement OPTN bylaw.
(e) Standard: Nutritional services. Nutritional assessments and diet counseling services furnished by a qualified dietitian must be available to all transplant patients and living donors. Definitions for a qualified dietitian included.	.....	No comparable OPTN policy/bylaw.
§ 482.96 Condition of participation: Quality assessment and performance improvement (QAPI). A transplant center must have a data-driven QAPI programs to monitor & evaluate performance of all transplantation services.	.....	No comparable OPTN policy/bylaw.
§ 482.98 Condition of participation: Human resources. (a) Standard: Director of a transplant center. Transplant center must be under the general supervision of a qualified transplant surgeon or a qualified physician-director.		

CROSSWALK OF TRANSPLANT CENTER FINAL RULE, PART 121, & OPTN POLICIES AND BYLAWS—Continued

CMS requirements	42 CFR Part 121, OPTN policies, and bylaws for transplant centers	Comments
(b) Standard: Transplant surgeon and physician. • Transplant center must identify to the OPTN a primary transplant surgeon and a transplant physician with the appropriate training and experience to provide transplantation services, who are immediately available to provide transplantation services when an organ is offered for transplantation. • Transplant surgeon is responsible for providing surgical services related to transplantation. • Transplant physician is responsible for providing and coordinating transplantation care.	OPTN Bylaw Appendix B defines the credential of a qualified transplant surgeon and physician in 15 pages. Each transplant center designated under 42 CFR 121.9(a)(2) must have on-site a qualified transplant surgeon.	The OPTN bylaw for credentials is too detailed for adoption in regulation. CMS requirement for ''immediate availability of the primary transplant surgeon & physician'' complement OPTN's ''on-site'' bylaw.
(c) Standard: Clinical transplant coordinator. The transplant center must have a qualified clinical transplant coordinator to ensure the continuity of care of patients and living donors throughout transplantation and donation.	OPTN Bylaw Appendix B: Requirement for a Clinical Transplant Coordinator with defined responsibilities.	CMS requirement complement the OPTN bylaw.
(d) Standard: Independent living donor advocate of living donor advocate team. The transplant center that performs living donor transplants must identify either an independent living donor advocate or an independent living donor advocate team to ensure protection of the rights of living donors and prospective living donors.		
(e) Standard: Transplant team. The transplant center must identify a multidisciplinary transplant team (composed of individuals from medicine, nursing, nutrition, social services, transplant coordination, and pharmacology) and describe the responsibilities of each member of the team.	§ 121.9(a) Designated Transplant Program Requirements. OPTN Bylaw Appendix B Attachment I. Collaborative Support—Transplant programs approved under 121.9(a)(2) must show evidence of collaborative involvement with experts in the field of hepatology, radiology, pediatrics, infectious disease, nephrology with dialysis capability, pulmonary medicine with respiratory therapy support, pathology, immunology, anesthesiology, physical therapy and rehabilitation medicine.	CMS requirements complement Part 121 requirements and OPTN bylaw.
(f) Standard: Resource commitment. The transplant center must demonstrate availability of expertise in internal medicine, surgery, anesthesiology, immunology, infectious disease control, pathology, radiology, and blood banking as related to the provision of transplantation services.	§ 121.9(a) Designated Transplant Program Requirements. Bylaws Appendix B Attachment I. Transplant Programs—Ancillary services—Transplant programs approved under 121.9(a)(2) must have immediate access to sophisticated microbiology, clinical chemistry, tissue typing, bloodbank support, radiology services, as well as the facilities required for monitoring immunosuppressive drugs.	CMS adopts the Part 121 requirements and OPTN bylaw.
§ 482.100 Condition of participation: Organ procurement. • Transplant center must ensure that transplant hospital has written agreement (with delineated responsibilities for both parties) with an OPO designated by the Secretary.	§ 121.9(a) Designated Transplant Program Requirements. Bylaws Appendix B Attachment I A transplant program approved under 121.9(a)(2) must have letters of agreement or contracts with an OPO.	CMS requirement complement the OPTN bylaw because the OPTN bylaw does not require transplant centers to notify the OPTN or CMS when an agreement with an OPO is terminated.
§ 482.102 Condition of participation: Patient and living donor rights. • In addition to meeting the requirements at § 482.13, the transplant center must protect and promote each transplant patient's and living donor's rights.	.....	No comparable OPTN policy/bylaw.
(a) Standard: Informed consent for transplant patients. • Transplant centers must have written policies for the informed consent process. • Each patient will be informed about: —The evaluation process; —The surgical procedure; —Alternative treatments;	.....	No comparable OPTN policy/bylaw.

CROSSWALK OF TRANSPLANT CENTER FINAL RULE, PART 121, & OPTN POLICIES AND BYLAWS—Continued

CMS requirements	42 CFR Part 121, OPTN policies, and bylaws for transplant centers	Comments
—Potential medical or psychosocial risks; —National & center-specific outcomes from the most recent SRTR center-specific report, including (but not limited to) the transplant center's observed and expected 1-year patient and graft survival, national 1-year patient and graft survival, and notification about all Medicare outcome requirements not being met by the transplant center; —Organ donor risk factors that could affect the success of the graft or health of the patient; —His or her right to refuse transplantation; —The fact that if his or her transplant is not provided in a Medicare-approved transplant center it could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid under Medicare Part B.		
(b) Standard: Informed consent for living donors. • Transplant centers must have written policies for the informed consent process. • Each living donor will be informed about: —The fact that communication between the donor & the transplant center will remain confidential, in accordance with the requirements at 45 CFR parts 160 & 164. —The evaluation process. —The surgical procedure, including post-op treatment. —The availability of alternative treatments for the transplant recipient. —The potential medical or psychosocial risks to the donor. —The national & center-specific outcomes for recipients & living donors as data are available. —The possibility that future health problems related to the donation may not be covered by the donor's insurance, and that the donor's ability to obtain health, disability, or life insurance may be affected. —The donor's right to opt out of donation at any time during the donation process. —The fact that if his or her transplant is not provided in a Medicare-approved transplant center it could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid under Medicare Part B.	.....	No comparable OPTN policy/bylaw. CMS adopts many of the informed consent elements contained in the Secretary's Advisory Committee on Transplantation (ACOT) Recommendations.

CROSSWALK OF TRANSPLANT CENTER FINAL RULE, PART 121, & OPTN POLICIES AND BYLAWS—Continued

CMS requirements	42 CFR Part 121, OPTN policies, and bylaws for transplant centers	Comments
(c) Standard: Notification to patients ..... Transplant centers must notify patients placed on the center's waiting list of information about the center that could impact the patient's ability to receive a transplant should an organ become available, and what procedures are in place to ensure the availability of a transplant team: —The fact the center is served by a single transplant surgeon or physician, the potential unavailability of the transplant surgeon or physician, and whether or not the center has a mechanism to provide an alternative transplant surgeon or transplant physician that meets the hospital's credentialing policies. • At least 30 days before a center's Medicare approval is terminated, whether voluntarily or involuntarily, the center must inform: —Patients on the waiting list & provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved center without loss of time accrued on the waiting list; and —Medicare beneficiaries on the center's waiting list that Medicare will no longer pay for transplants performed at the center after the effective date of the center's termination of approval. • As soon as possible prior to a transplant center's inactivation, the center must inform patients on the center's waiting list and, as directed by the Secretary, provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list.	§ 121.9 Designated Transplant Program Requirements. (a) To receive organs for transplantation, a transplant program approved under 121.9(a)(2) agrees to promptly notify OPTN & patients awaiting transplantation if it becomes inactive. OPTN Bylaws Appendix B Attachment I—Criteria for Institutional Membership. III.C Transplant programs—A transplant program served by a single surgeon or physician shall inform patients of this fact and potential unavailability of 1 or both of these individuals during the year. OPTN Bylaws, Appendix B. VI. Change in Program Status. When a transplant program is voluntarily or involuntarily inactivated, waitlist patients may retain existing waiting time and continue to accrue waiting time. Accrued waiting time may be transferred to the patient's credit when s(he) is listed with a new program.	CMS adopts Part 121 and OPTN bylaws.
§ 482.104 Condition of participation: Additional requirements for kidney transplant centers. (a) Standard: End stage renal disease (ESRD). • Kidney transplant centers must furnish directly transplantation & other medical & surgical specialty services required for the care of ESRD patients. (b) Standard: Dialysis services. • Kidney transplant centers must furnish inpatient dialysis services directly or under arrangement. (c) Standard: Participation in network activities. • Kidney transplant centers must cooperate with the ESRD Network designated for its geographical area, in fulfilling the terms of the Network's current statement of work.	.....	No comparable Part 121 requirements or OPTN policy/bylaw for kidney transplant centers.
No comparable CMS requirements	Bylaws Appendix B—Criteria for Institutional Membership. III.E Relocation and Transfer of Established Programs.	Relocation and transfer of established programs is not addressed in CMS requirements.
No comparable CMS requirements	Part 121.8 Allocation requirements of Organs. OPTN Policy 3.0 Organ Distribution. 3.3 Acceptance Criteria. 3.4 Organ Procurement, distribution, and alternative systems for organ distribution or allocation. 3.9 Allocation System for Organs Not Specifically Addressed.	The OPTN policies are all organ allocation/acceptance policies.

CROSSWALK OF TRANSPLANT CENTER FINAL RULE, PART 121, & OPTN POLICIES AND BYLAWS—Continued

CMS requirements	42 CFR Part 121, OPTN policies, and bylaws for transplant centers	Comments
	3.10 Back-up for Inactive Transplant Programs. 3.11 Intestinal Organ Allocation. Appendix to Policy 3.0. A. HLA Antigen Values and Split Equivalences. C. Resolving Discrepant Donor and Recipient HLA Typing Results in the OPTN Database. Policy 4.0 Acquired Immune Deficiency Syndrome (AIDS) and Human Pituitary Deceived Growth Hormone (HPDGH) and Human T-Lymphotropic Virus Type I (HTLV–I). Policy 6.0 Transplantation of Non-Resident Aliens.	
§ 488.61 Special procedures for approval and re-approval of organ transplant centers. • Survey, certification, and enforcement procedures at 42 CFR part 488, subpart A, including the periodic review of compliance and approval contained in § 488.20. • Transplant centers that meet all data submission, clinical experience, outcome, and process requirements will be approved for 3 years. • Current Medicare-approved centers will continue to be Medicare approved after submitting applications and awaiting CMS's decision for approval. • At the end of 3-year approval period, CMS will review transplant center's data to determine compliance with data submission, clinical experience and outcome requirements at § 482.82. • If a center is in compliance with § 482.82, CMS may choose to review its compliance with the rest of the CoPs. • A transplant center may remain inactive and retain its Medicare approval for a period not to exceed 12 months during the 3-year approval cycle. • Centers that have lost their Medicare approval may seek re-entry into the Medicare program at any time, and the center must: (1) Request initial approval; (2) Comply with the initial approval requirements; and (3) Submit a report to CMS documenting any changes or corrective actions taken by the center as a result of the loss of its Medicare approval status. Part 498 Appeals procedures for determinations that affect participation in the Medicare program and for determinations that affect the participation of ICFs/MR and certain NFs in the Medicaid program. • The definition of ''provider'' is amended by adding ''transplant center'' after ''hospital'' the first time it appears.	§ 121.10(c)(1)(2) Enforcement of OPTN rules. Sanctions for violations of non-mandatory policies or mandatory policies (w/o approval from the Secretary of DHHS) include: • Warning, letter of admonition, or letter of reprimand. • Probation. • Member Not in Good Standing. Additional Sanctions (only for violation of mandatory policies): • Suspension of member privileges. • Termination of OPTN membership. • Termination of Status as Designated Transplant Program, Termination of Participation in Medicare/Medicaid, Termination of Reimbursement under Medicare/Medicaid. The 3 additional sanctions can only be imposed by the Secretary. § 121.10(c) Sanctions can also be imposed for violations of Part 121, including its data submission requirements, and when the Secretary determines that the public health or patient safety is at risk.	OPTN policies and bylaws are voluntary, until approved (i.e., codified) by the Secretary. At this time, the Secretary has not approved or published any OPTN policies and bylaws, except for data submission requirements. For the first time, transplant centers have the same appeal rights as other Medicare providers.

CMS Oversight and OPTN Policies

Some commenters voiced their opinions about our oversight of transplant centers in comparison to OPTN oversight of its transplant hospital members.

Comment: Some commenters stated their appreciation that the proposed rule is congruent with OPTN policies and bylaws, because OPTN policies and bylaws were developed through a consensus process with broad participation by the transplant community. Commenters pointed out that the rule sets consistent and unified standards and provides an established infrastructure for performance monitoring and review of transplant centers.

Response: The OPTN's primary responsibilities are to ensure the effectiveness, efficiency, and equity of

organ allocation; increase the supply of transplantable organs; collect and disburse data; and designate transplant programs. We are responsible for establishing minimum standards to protect patient health and safety, and for implementing oversight mechanisms to ensure that transplant centers provide quality transplant and living donor care to Medicare beneficiaries through the development of health and safety requirements. In developing this rule, we worked closely with HRSA, which oversees the OPTN and SRTR, to ensure consistency and minimize the burden on transplant centers where possible.

Comment: A commenter requested that we limit our role to reimbursement of clinical services.

Response: As a health care regulatory agency and a prudent health care purchaser, our responsibility cannot be limited to reimbursement. The Secretary has the statutory authority and responsibility to protect patient health and safety and to ensure that high quality care is provided to patients.

Comment: Many commenters stated that the OPTN oversight process and our approval and re-approval process would create an inconsistent and duplicative mechanism in the oversight of transplant centers. The commenters stated that we should collaborate with the OPTN to streamline the two processes into one unified consistent process, but with more reliance on OPTN oversight. One public commenter stated that CMS should consider termination of a center only if the OPTN Board reports to the Secretary that it has made a final decision to take adverse action against the center. A peer reviewer was concerned that the collegial relationship between OPTN and the transplant centers might be jeopardized by codification of some of the OPTN requirements.

Response: We understand the commenters' concerns. However, for the most part, we and the OPTN have different roles vis-á-vis transplant centers. For example, when surveying transplant centers for compliance with the CoPs in this final rule, we will focus on protections for patient health and safety. When the OPTN surveys (or performs desk audits of) transplant centers, it focuses on compliance with candidate listing and delisting, data submission, and its patient notification policies and verifies that the designated physician and surgeon are the same individuals approved by the OPTN. The degree of authority to act in the event of non-compliance also differs. The OPTN generally takes a collegial approach and assists centers in improving their performance, while we generally take a regulatory approach which sometimes may lead to termination of the Medicare agreement with providers. However, compliance with the OPTN's policies will facilitate transplant centers' compliance with the requirements in this final rule. Therefore, the OPTN will continue to play a consultative role with transplant centers to assist them in complying with Medicare requirements. We believe the collegial relationship between the OPTN and the transplant centers may be enhanced and strengthened rather than compromised.

Comment: Many commenters stated that the OPTN oversight process is vigorous and effective and that the OPTN should have full oversight of transplant centers to avoid duplicative efforts. The commenters cited 42 CFR part 121 as the regulation governing the operation of the OPTN and stated that the OPTN has legally binding rules enforceable on transplant centers.

Other commenters noted that the OPTN already surveys heart and liver programs once every 3 years. The commenters recommended that the OPTN be recognized as the accrediting body to audit and survey centers periodically based on its expertise in dealing with the complexity of transplantation. A commenter recommended that we review a center for potential termination from the Medicare program only if the Secretary has been notified of a final decision of the OPTN Board to take an adverse action against the center. The commenters stated that reviews or surveys conducted by an inexperienced CMS designee would burden centers and lead to misinterpretation of OPTN policies and CMS regulations, which could cause confusion and loss of Medicare approval.

Response: The commenters are correct that 42 CFR part 121 governs the operation of the OPTN, which establishes policies for transplant hospital members. OPTN policies are enforceable only when they have been incorporated into regulations by the Department. However, with the exception of the OPTN data submission requirements, OPTN policies have not been incorporated by the Department. Therefore, if the OPTN determines that removal of a member's designation as a transplant hospital is warranted for reasons of non-compliance with other OPTN policies, with the final rule governing the operation of the OPTN (42 CFR part 121), or because of a threat to public health and safety, the OPTN will recommend to the Secretary that the member's designation be revoked. The OPTN has made this recommendation on only two occasions.

We have an obligation to oversee transplant centers serving Medicare beneficiaries, and we do not have the statutory authority to delegate oversight responsibilities to the OPTN. In our view, the OPTN oversight approach is a complement to the Medicare regulatory authority. Once the final rule becomes effective, and before conducting surveys, our surveyors will be trained in applicable OPTN policies for transplant centers.

Comment: A commenter recommended that the Secretary take action to expand the role of the OPTN relative to oversight of living donors.

Response: The commenter's recommendation falls outside the scope of this final rule. We will forward this recommendation to the Secretary for consideration.

Comment: A commenter stated that despite the fact that the OPTN requires transplant programs to abide by OPTN policies and bylaws, we should not codify the OPTN policies and bylaws as regulatory language. One commenter stated that the relatively fluid OPTN policies and bylaws would allow the incorporation of future changes in transplant practice more quickly.

Response: The requirements in this final rule are intended to be broadly applicable to transplant centers over a long period of time. OPTN policies or elements of OPTN policies that we have included in this final rule conform to this intent. We understand that many OPTN policies, particularly organ allocation, transplant surgeon and transplant physician credentials, and criteria for listing and de-listing transplant candidates are subject to rapid changes as transplant medicine advances. Therefore, we did not include such policies in this final rule.

Comment: Some commenters raised confidentiality concerns regarding the sharing of data between the OPTN and CMS under applicable laws and regulations protecting the peer review process. One commenter suggested adding language to state that the regulation is not intended to affect the confidentiality of the process in any manner.

Response: We understand the commenters' concerns about the confidentiality of data shared between the OPTN and CMS. However, under reporting requirements set forth in 42 CFR 121.11(b)(1)(iii), the OPTN and the SRTR are required to provide to CMS any data that we request, as appropriate. Nonetheless, it is not our intention to disrupt the OPTN confidential peer review process. We will obtain only the

OPTN data that is necessary for our oversight of transplant centers.

Comment: One commenter suggested that section 1865 of the Act and regulations at 42 CFR part 488 mean that only CMS's designated national accrediting organizations are eligible for deeming authority for transplant centers. The commenter further stated that organizations that accredit both hospitals and transplant centers are in the best position to ensure consistent quality oversight and avoid fragmented survey arrangements.

Response: We will consider applications from any national accrediting organization for deeming authority for initial approval and re-approval for any of the extra-renal transplant centers. We believe that we have the statutory authority to permit national accrediting organizations to accredit most transplant centers as ''facilities,'' pursuant to paragraph 1865(b)(4) of the Act, with the exception of kidney transplant centers. As discussed previously, section 1864 of the Act authorizes the use of State agencies to determine providers' compliance with the CoPs. A national accreditation program may apply for deeming authority for the providers that are specifically listed in § 488.6. Since ''transplant centers'' are not specifically identified in § 488.6, this final rule inserts the language ''transplant centers, except for kidney transplant centers'' in § 488.6(a) with the list of providers eligible for deeming authority. Kidney transplant centers are specifically excluded because they are not eligible for deeming authority by statute. (See sections 1864 and 1865(b)(4) of the Act.)

Special Requirements for Transplant Centers (Proposed § 482.68)

We proposed that a transplant center located within a hospital that has a Medicare provider agreement must meet the CoPs specified in § 482.72 through § 482.104 in order to be granted our approval to provide transplant services.

We proposed that the CoPs specified in § 482.72 through § 482.104 would apply to all heart, heart-lung, intestine, kidney, liver, lung, and pancreas transplant centers, unless specified otherwise.

We also proposed that transplant centers seeking Medicare approval must meet the hospital CoPs specified in § 482.1 through § 482.57.

We received no comments on this section of the proposed regulation and are finalizing it as proposed.

Definitions (Proposed § 482.70)

We proposed definitions for ''transplant hospital,'' ''transplant program,'' and ''transplant center'' to clarify the usage of these terms throughout the regulation.

We proposed deleting the definitions for ''histocompatibility testing,'' ''ESRD Network,'' ''network organization,'' ''organ procurement,'' ''renal transplantation center,'' ''transplantation service,'' and ''transplantation surgeon'' contained in § 405.2102, as these terms are no longer used in the section.

We proposed including the definitions for ''ESRD,'' ''ESRD network,'' and ''network organization'' from § 405.2102 in this final rule to emphasize the distinct statutory authority and requirements that kidney transplant centers have to meet and to clarify the use of the terms in the proposed CoPs for transplant centers.

We proposed adding definitions for ''adverse event,'' ''heart-lung transplant center,'' ''pancreas transplant center,'' and ''intestinal transplant center.''

This final rule includes all definitions related to ESRD Network programs from 42 CFR part 405, subpart U, § 405.2102, as well as §§ 405.2110 through 2114. We note that in the proposed rule we incorrectly stated that our proposed definition for ''adverse event'' was derived from the JCAHO's definition of ''adverse event.'' In fact, JCAHO has a definition for ''sentinel event'' but not ''adverse event.'' Additionally, we have made a change to the definition of ''adverse event'' for clarification purposes. The proposed definition listed two examples of adverse events related to living donors: ''living donor death due to mismanagement of the donor'' and ''avoidable loss of a healthy living donor.'' We have replaced these two examples with ''serious medical complications or death caused by living donation'' to clarify that the death of any living donor or a living donor's serious medical complications caused by living donation should be investigated as an adverse event. Following are summaries of the comments we received and our responses.

Comment: One commenter applauded our efforts to standardize definitions for transplant hospitals for the purpose of improving communication. The commenter noted that JCAHO developed a Patient Safety Event Taxonomy in response to the lack of agreement on definitions regarding medical errors. The commenter suggested that the adoption of the Patient Safety Event Taxonomy developed by the JCAHO in the quality assessment and performance improvement (QAPI) CoP would decrease confusion, improve patient safety, and promote quality.

Response: A Patient Safety Event Taxonomy is a system of classifying adverse events at hospitals or other providers of health care. Thus, the Taxonomy is a ''language'' in which providers can report adverse events. One of the JCAHO's current initiatives is to ''promote using health information technology to improve patient safety reporting, data analysis and learning from errors, and to promote a national reporting system for adverse events through the use of standardized patient safety taxonomy and ontology.'' Although the final rule provides a general definition for an ''adverse event'' in transplantation, it does not attempt to classify all possible adverse events in health care or transplantation. The Patient Safety Event Taxonomy classifies all health care events, not just those related to transplantation. Incorporation of the Taxonomy into the QAPI CoP would be inappropriate because it falls outside the scope of this rule. Therefore, we have not adopted the commenter's suggestion.

Comment: One commenter noted that the term ''transplant center'' is commonly used interchangeably with the term ''transplant hospital.'' For this reason, the commenter stated that our proposal to use the term ''transplant center'' interchangeably with ''transplant program'' is confusing and the commenter suggested the removal of the term ''transplant center'' in the final rule.

Response: Although we agree that these terms often are used interchangeably, we believe the transplant community understands our use of the term ''transplant center'' in this final rule. We do not believe it is necessary to make a change based on this comment.

Proposed General Requirements for Transplant Centers

Condition of Participation: OPTN Membership (Proposed § 482.72)

We proposed that a transplant center must be located in a transplant hospital that is a member of, and abides by the rules and requirements of, the OPTN, as set forth at § 482.45(b)(1), and that are enforceable under 42 CFR 121.10.

We proposed that no transplant hospital would be considered to be out of compliance with section 1138(a)(1)(B) of the Act (which requires participation in the OPTN) unless the Secretary gave the OPTN formal notice that he or she approved the decision to exclude the transplant hospital from the OPTN and notified the center in writing.

We received no comments on this section of the proposed rule. Therefore, we are finalizing it as proposed.

Condition of Participation: Notification to CMS (Proposed § 482.74)

We proposed requiring each transplant center to notify us immediately of any significant changes related to the center's transplant program or any change that would otherwise alter specific elements in its application for approval or re-approval.

We proposed that instances in which we should be notified would include, but not be limited to, changes in key staff members of the transplant team (such as the individual who has been designated to the OPTN as the center's primary transplant surgeon or physician) or a decrease in the center's volume or survival rate that could result in the center being out of compliance with § 482.82.

Note that in this final rule, we have added to this section two specific instances that must be reported to us immediately. First, a transplant center must notify us if the hospital in which it is located terminates its agreement with an OPO for recovery and receipt of organs. Further information about this requirement can be found in this preamble in our discussion of the CoP for organ procurement. Second, a transplant center must notify us if it becomes inactive. Further information about our requirements in regard to transplant center inactivity can be found in this preamble in our discussion of clinical experience requirements and special procedures for approval and re-approval of organ transplant centers.

For clarity, we have replaced the language stating that a transplant center must notify us of any change that would otherwise alter specific elements in its application for approval. Section 482.100 of this final rule states that, ''a transplant center must notify CMS immediately of any significant changes related to the center's transplant program or changes that could affect its compliance with the conditions of participation.''

Following are summaries of the comments we received and our responses.

Comment: A number of commenters supported the requirement for transplant centers to notify us of significant changes that may affect their approved status. However, some commenters stated that the requirement would be redundant and burdensome because the OPTN already requires such notification.

Response: The OPTN bylaws require transplant hospital members to notify the OPTN immediately if the hospital learns that its primary surgeon or primary physician plans to leave. The transplant hospital is required to submit to the OPTN the name of the replacement surgeon or physician, curriculum vitae, and documentation of credentials and qualification at least 30 days (if possible) prior to the departure of the individual being replaced.

Although we have avoided duplicating OPTN policies in this final rule (unless we have done so deliberately so that we can enforce a requirement), in this instance, we believe a transplant center should inform us in addition to the OPTN so that we can actively monitor the situation to confirm that the departing surgeon or physician is replaced. We note that the current NCDs require Medicare-approved heart, liver, and lung centers to report such information to us.

Comment: One commenter suggested that transplant centers should not be required to notify us of a significant decrease in volume or survival rates. The commenter stated that an unusually large number of early deaths may not significantly affect 1-year outcomes if the transplant center subsequently has increased volume with successful results. Furthermore, these outcomes will be reflected in the subsequent SRTR 1-year survival reports.

Response: As one component of the active monitoring and oversight of transplant centers, we need to be made aware of any significant changes at transplant centers. However, the outcome requirements in this final rule are based on 1-year patient and graft survival as calculated and reported by the SRTR, meaning that there may be a considerable lapse of time before we have access to data from the SRTR indicating that a transplant center's outcomes have dropped significantly. Although we understand that a decrease in clinical experience (that is, volume) and survival rates within a short period of time does not necessarily signify a problem, we need to be aware of these changes so that we can determine whether they are meaningful, for example, whether a decrease in the number of transplants signals ongoing inactivity and whether a decrease in outcomes signals a significant problem.

When notified by a transplant center of a significant change, we will assess the information to determine how to proceed. We may note the information (such as a change in staff) and take no further action, contact the center for more information, analyze the information in conjunction with HRSA and the OPTN, and/or conduct an on-site review of the center.

We recognize that it may be challenging for centers to determine whether decreases in the volume and unadjusted survival rates would be significant enough to warrant reporting to CMS. Centers will not be required to independently decide what constitutes a significant change. Centers will receive guidance from CMS through interpretive guidelines and provider notifications as to what constitutes a significant enough decrease in clinical experience or survival rates to necessitate reporting. This guidance is under development.

Interpretive guidelines provide guidance to Medicare surveyors and clarify the intent of regulations. Each provider type is surveyed in accordance with the appropriate protocols based on the substantive requirements in the statute and regulations to determine whether a citation of non-compliance is appropriate. A center will be deemed deficient if it fails to meet the requirements of the statute or regulations, which, in turn, are based on the surveyor's observations of the providers' performance or practices.

The specific process that surveyors use for each type of provider or supplier is outlined in the CMS State Operations Manual. The State Operations Manual is publicly available under the ''Manuals'' section of the CMS Web site. Included in the appendices of the State Operations Manual are the Interpretive Guidelines (also known as ''Guidance to Surveyors'') for each type of provider or supplier. The Interpretive Guidelines interpret and clarify the Conditions and Standards that are outlined in statute and regulations. The Interpretive Guidelines merely define or explain the relevant statute and regulations and describe the specific elements that a surveyor will be reviewing and/or observing. The Interpretive guidelines do not impose any requirements that are not otherwise sets forth in statute or regulation.

Implementation of the survey and certification process for transplant programs will follow this same process. CMS is developing revisions to the State Operations Manual and a separate appendix that will include the Interpretive Guidelines that will be used for surveyors of organ transplant programs. CMS will also be posting informational material on its Web site for providers that would like to request approval for their transplant program. We made no changes based on this comment.

Comment: One commenter noted that there was no definition provided for the term ''immediately'' for purposes of

describing the time frame within which a transplant center must notify us of changes. Other commenters questioned the term ''significant changes'' and recommended that the definition should be limited to staff changes and adverse events.

Response: We disagree that the scope of significant changes should be limited to staff changes and adverse events. As we said in our previous response, decreases in the number of transplants performed and in the number of positive outcomes are also significant changes.

We will address the time frame within which a transplant center must notify us of any significant changes and the meaning of ''significant changes'' in our interpretive guidelines for Medicare surveyors, as that medium permits a more thorough explanation of our expectations. Interpretive guidelines provide guidance to surveyors and serve to clarify and explain the intent of regulations. No changes were made based on this comment.

Comment: One commenter inquired about the consequence of failure to comply with this requirement. The commenter stated that a good faith failure to comply should not constitute grounds for termination.

Response: Notification to us is one of the conditions of participation required for Medicare-approved transplant centers. A center that fails to notify us of any significant changes as delineated in § 482.74 would be considered non-compliant with the transplant conditions of participation and 42 CFR part 488, may be subject to investigation, and could ultimately have its transplant center approval revoked.

Comment: One commenter asked for a CMS contact for notification of changes. A commenter suggested linking transplant centers' notification of changes to the appropriate accrediting organization so that further assessment of the situation can be conducted promptly.

Response: At this time, we do not know whether we or a designee will survey transplant centers. Therefore, under this final rule, a transplant center must report a significant change to us. (See § 482.74.)

Comment: A commenter asked how we will communicate the changes in primary surgeons and physicians to the OPTN, once notified by transplant centers of the change.

Response: The OPTN policies that transplant centers must meet as OPTN members already require transplant centers to inform the OPTN of changes in primary surgeons and physicians immediately; therefore, there is no need for us to communicate such changes to the OPTN.

Condition of Participation: Pediatric Transplants (Proposed § 482.76)

Children are eligible for Medicare on the basis of ESRD as follows: under section 226A of the Act, an insured worker's dependent child (as defined in regulations) who is medically determined to have ESRD is eligible for Medicare Part A and Part B. According to 42 CFR 408.13, a child is considered ''dependent'' if he or she is unmarried and is under the age of 22 or is between ages 22 and 26 and has been receiving at least one half of his or her support from the insured worker continuously since before attainment of age 22.

Children are eligible for Medicare on the basis of disability as follows: (1) Under section 223(b) of the Act, individuals who have been entitled to Childhood Disability Benefits (CDB) under section 202(d) of the Act by reason of a disability (as defined in section 223(d) of the Act) for 24 months are entitled to Medicare Part A and Part B the 25th month of disability benefit entitlement. Section 202(d) restricts the first month of CDB entitlement to the month the child attains age 18. Therefore, the earliest month a CDB beneficiary can qualify for Medicare is the month he or she attains age 20; or (2) section 223 of the Act provides that any individual who is under age 65 and has the necessary Social Security work credits, as defined in section 223(c) of the Act, and is under a disability as defined in section 223(d) of the Act, is entitled to Medicare Parts A and B on the 25th month of disability benefit entitlement.

In 2005, Medicare paid for 404 pediatric transplants of different organ types.

We proposed that in order to be reimbursed for transplants performed on pediatric Medicare beneficiaries, a hospital that furnishes transplantation services to both adult and pediatric patients must seek separate Medicare approval to provide pediatric transplantation services.

We also proposed retaining the statutory criteria found at section 4009(b) of the Omnibus Budget Reconciliation Act (OBRA) 1987 (Pub. L. 100–203) as an extra option for heart transplant centers that wish to become Medicare-approved to perform pediatric heart transplants. We did not reference this citation in the proposed rule as an oversight. We proposed that a center that wishes to become Medicare-approved to perform pediatric heart transplants may also be approved by meeting data submission, outcome, and process requirements in the final rule.

We proposed that a center that performs 50 percent or more of its transplants on adult patients must be approved to perform adult transplants in order to be approved to perform pediatric transplants. For these centers, we proposed that a loss of Medicare approval to perform adult transplants, whether voluntary or involuntary, would result in a loss of the center's approval to perform pediatric transplants. We also proposed that a loss of Medicare approval to perform pediatric transplants, whether voluntary or involuntary, would not impact the center's Medicare approval to perform adult transplants.

We proposed that a center that performs 50 percent or more of its transplants on pediatric patients must be approved to perform pediatric transplants in order to be approved to perform adult transplants. For these centers, we proposed that loss of Medicare approval to perform pediatric transplants, whether voluntary or involuntary, would result in a loss of the center's approval to perform adult transplants. We proposed that loss of Medicare approval to perform adult transplants would not impact the center's Medicare approval to perform pediatric transplants.

For a center that performs 50 percent or more of its transplants on pediatric patients, we proposed that there would be no minimum number of adult or pediatric transplants required prior to its request for Medicare approval. Following are summaries of the comments we received and our responses.

Comment: A commenter noted that it is important for pediatric transplant centers to continue to transplant adolescent and young adults beyond the pediatric age range (18–25) to maintain continuity of care of established patients.

Response: We agree. In some situations, a young adult for whom an organ becomes available has received treatment for end stage organ failure from the same pediatric transplant surgeon and pediatric transplant physician for many years and understandably wishes to have the transplant performed at the pediatric center where these physicians practice.

Under the proposed rule and this final rule, which require separate Medicare approvals for performing adult and pediatric transplants, a transplant center performing predominately pediatric transplants will be able to transplant adolescents and young adults age 18 and older. We recognize that pediatric

programs may need to continue transplanting young adults beyond the pediatric age range in order to maintain continuity of care for established patients. The health care needs of these patients are best addressed in a pediatric setting until appropriate transition to adult care can occur. Pediatric centers are required to become certified as both a pediatric and adult transplant center if they intend to provide transplantation services to both populations.

Comment: A few commenters agreed that pediatric centers should meet the transplant center conditions of participation, but they did not agree that adult and pediatric centers should be approved separately. The commenters noted that the low volume of adult transplants performed at pediatric centers does not justify the cost and labor for the centers to seek separate approval to perform adult transplants. Likewise commenters said it would be burdensome to require an adult center to seek separate Medicare approval just to perform a few pediatric transplants.

Response: We understand the commenters' concerns. In our view, a center that performs 50 percent or more of its transplants on adult patients in a 12-month period is considered to be an adult transplant center whereas a center that performs 50 percent or more of its transplants on pediatric patients in a 12-month period is considered to be a pediatric transplant center. There are distinct differences between adult centers performing occasional pediatric transplant and pediatric centers performing occasional adult transplants in terms of patient selection criteria, patient management, and the number of transplants performed. Because of these differences, we believe that approving adult and pediatric centers as one unified program is problematic. For example, it would be difficult, if not impossible, for pediatric centers to meet clinical experience requirements that are appropriate for adult transplant centers, which could impair access to pediatric transplants.

However, we will permit a transplant center to submit its request for approval as a pediatric transplant center and its request for approval as an adult transplant center using the same application, which should *minimize the paperwork burden.* We made no changes based on this comment.

Comment: Some commenters stated that in most pediatric centers, the core transplant team performs both adult and pediatric transplants. The commenters said that to be consistent with OPTN requirements for pediatric centers, we should allow the sharing of personnel in transplant hospitals that have both adult and pediatric transplant programs. Some commenters recommended treating adult and pediatric transplant centers as one unified program or adopting the statutorily-based approval criteria as used in pediatric heart transplant centers.

Response: We recognize that many centers that perform pediatric transplants are operated by, or affiliated with, a Medicare-approved adult transplant center. In some transplant centers, the core transplant team performs both adult and pediatric transplants. We have no objection to such arrangements, provided that a transplant center has committed sufficient resources to both its pediatric and its adult transplant programs. There is nothing in the final rule that precludes a pediatric center and an adult center from operating as one unified program. Nevertheless, we would emphasize that an adult transplant center may not attempt to meet the clinical experience requirement by combining the number of adult transplants it has performed with pediatric transplants that were performed at its pediatric center. The outcomes of pediatric and adult transplant centers are reviewed separately.

Comment: A commenter recommended adopting the OPTN pediatric transplant standards.

Response: OPTN pediatric transplant policies relate primarily to pediatric organ allocation, and transplant surgeon and physician training and experience, and they differ significantly from our proposed CoPs for pediatric centers. We did not make any changes based on the comment.

We received no comments on our proposal to allow a heart transplant center to provide transplantation services to pediatric heart patients to be approved to perform pediatric heart transplants by meeting the OBRA 1987 criteria in section 4009(b) (Pub. L. 100–203). Therefore, the proposal was finalized without change except for the addition of the OBRA 1987 citation.

Condition of Participation: Data Submission, Clinical Experience, and Outcome Requirements for Initial Approval of Transplant Centers (Proposed § 482.80)

We proposed that transplant centers must meet all of the data submission and outcome requirements in order to be granted our initial approval. If a center failed to meet any of the requirements, no waiver would be granted. However, we did propose certain exceptions, which are discussed below.

Proposed Data Submission Requirements

We proposed at § 482.80(a) that no later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of required data submissions on all transplants (deceased and living donor) that the center has performed at the center.

We proposed that required data submissions would include, but not be limited to, the submission of the appropriate organ-specific OPTN forms for transplant candidate registration, transplant recipient registration, and transplant recipient follow up.

We proposed using the same data submission requirements for both initial approval and re-approval.

Proposed Outcome Requirements

We proposed using the same outcome requirements for both initial approval and re-approval.

We proposed using the SRTR's center-specific reports as the foundation of our outcome evaluation system. We proposed reviewing outcomes for all transplants performed at a center, including outcomes for living donor transplants, if applicable. With the exception of lung transplants, we will review adult and pediatric outcomes separately when a center requests Medicare approval to perform both adult and pediatric transplants. The OPTN policies for the cutoff for pediatric lung allocation and outcome assessment is under 12 years old, and the number of pediatric (under 12 years old) lung transplants is very small. Therefore, the outcomes of pediatric lung transplants and adult lung transplants are reviewed together. We proposed that we would compare each transplant center's observed number of patient deaths and graft failures 1-year post-transplant to the center's expected number of patient deaths and graft failures 1-year post-transplant (or under certain circumstances, 1-month post-transplant patient and graft survival in lieu of 1-year post-transplant patient and graft survival.)

We proposed that under most circumstances, an adult transplant center requesting Medicare approval would need to have 1-year patient and 1-year graft survival follow-up data on at least 9 transplants of the appropriate organ type during the 2.5 year period reported in the most recent SRTR center-specific report.

We proposed that we would compare each transplant center's observed

number of patient deaths and graft failures 1-year post-transplant to the center's expected number of patient deaths and graft failures 1-year post-transplant using the data contained in the most recent SRTR center-specific report, as long as the center had 1-year post-transplant follow up on at least 9 transplants of the appropriate organ type. We also proposed that if a center's observed patient survival or graft survival rate was lower than the expected patient or graft survival rate and the center crossed over all 3 of the non-compliance thresholds for all 3 tests (p-value less than 0.05, observed—expected greater than 3, and observed/expected greater than 1.5) for either graft or patient survival, we would not consider the center to be in compliance with the outcome requirements.

We proposed that a heart-lung transplant center, an intestine transplant center, and a pancreas transplant center, as defined in the final rule, would not be required to comply with the outcome requirements for re-approval.

We proposed that a center requesting Medicare re-approval to perform pediatric transplants would not be required to perform a minimum number of pediatric transplants prior to its request for Medicare re-approval.

Comment: Some commenters supported the proposed data submission requirements. The commenters were pleased that the provisions would not require additional data beyond the OPTN requirements. The commenters asked us to emphasize that follow-up data are essential for evaluating and reporting of outcomes and the refinement of organ allocation policies.

Response: We appreciate the commenters' understanding of the importance of data submission in the accurate assessment of transplant center performance. We did not propose and are not requiring under this final rule that transplant centers report additional data beyond what they already report to the OPTN. The OPTN's comprehensive data reporting policies provide sufficient data for us to determine whether transplant centers meet the outcome measures in this final rule.

Comment: A commenter stated that we should coordinate our data submission requirements with the OPTN's, so that centers do not have to submit data both to us and to the OPTN.

Response: Under this final rule, we require transplant centers to continue to submit the required data to the OPTN UNet℠ system (or any successor system under the OPTN Contract) in accordance with the specified time frame. UNet℠ is a secure system for transplant hospitals to communicate transplant information and data to UNOS. We are not requiring transplant centers to submit data to us separately on a routine basis.

Comment: A commenter stated that compliance with the data submission requirements should not be used as the basis for denial of Medicare approval and re-approval. The commenter said that there is no evidence linking failure to submit OPTN-required data with poor outcomes.

Response: Given that the national and center-specific outcome measures calculated by the OPTN are based largely on data submitted by the transplant centers, it is imperative for centers to report data to the OPTN completely, accurately, and in a timely manner. We cannot provide meaningful oversight of center activities without complete and timely data submission. To ensure that the data used by the SRTR for analysis and compilation of the national and center-specific reports are comprehensive and accurate, we must have data submission requirements. We made no changes based on this comment.

Comment: Some commenters expressed concern that the expanding scope and complexity of OPTN data submission have significant personnel and financial implications for transplant centers. The commenters urged us to confer with the OPTN to limit the Federal data submission requirements to data needed only to calculate 1-year post-transplant outcomes.

Response: We understand the administrative workload required to achieve compliance with OPTN data submission policies. In 2006, the OPTN engaged in an extensive effort to review all data elements currently submitted by transplant centers to determine whether the number of elements could be reduced to lessen the burden on centers. Based on collaboration with the American Society of Transplant Surgeons and the American Society of Transplantation and input from the public, the OPTN succeeded in reducing the data entry burden on its transplant hospital members. For example, 268 data fields will no longer be required for validation of UNet℠ forms, such as the transplant candidate registration form and the transplant recipient registration and follow up forms. Additionally, the requirement to follow transplant recipients for 2 years after graft failure has been eliminated. With significant reduction in data submission elements such as these, the OPTN anticipates that data quality will improve significantly. We continue to support the OPTN's commitment to review its data collection process annually for opportunities to reduce burden.

However, we believe that the data submitted by transplant centers cannot be limited only to those data needed to calculate 1-year post-transplant outcomes. The more extensive data submitted by transplant centers form the backbone for the research and analyses produced by the SRTR, and the data are necessary for the OPTN, CMS, and transplant centers to develop sound policies. No changes were made based on this comment.

Comment: Some commenters requested that we quantify whether ''95 percent compliance'' means 95 percent of forms, patients, or data fields. A commenter suggested a data compliance threshold of less than 95 percent.

Response: By 95 percent compliance, we mean that 95 percent of the OPTN-required forms on all transplants (deceased and living donors) must be completed and submitted within 90 days following the OPTN-required time frame. This requirement provides transplant centers with an additional 90 days beyond the OPTN due date to comply. In our view, lowering the threshold to less than 95 percent is unacceptable and inconsistent with OPTN requirements. Therefore, we did not make any changes based on this comment.

Comment: A commenter recommended that if a center produces independent evidence that it has submitted the required data timely or if a center's failure to produce the required data is attributable to unique circumstances that are unlikely to recur, we should consider the center to be compliant with data submission requirements. One commenter stated that the imposition of the ''no later than 90 days after the OPTN due date'' deadline is unnecessarily harsh and recommended that, as long as a transplant center submits 95 percent of the required 1-year data in time to be included in the SRTR report, we should consider the transplant center to be compliant. Another commenter expressed concern that tying Medicare approval to compliance with the 95 percent data submission requirement would result in centers submitting poor quality data. The commenter suggested that in an effort to comply, centers may resort to marking data elements as ''unknown'' or ''lost to follow up'' more often than is currently done.

Response: Data submission policies that differ from those of the OPTN are likely to confuse transplant centers and result in decreased compliance with OPTN policies. When reviewing a center's compliance with the data

submission requirements, we will take into consideration whether circumstances beyond the control of the center prevented it from fully complying with the data submission policies. Nevertheless, any willful falsification of data by a transplant center will be considered a violation of the data submission requirements in this final rule, as well as that of 42 CFR 121.11(b)(2).

Comment: Some commenters asked that we exempt kidney transplant centers from data submission and outcome requirements because kidney transplants are covered under the Act.

Response: The Act provides the authority for Medicare to pay for kidney transplantation. However, it does not preclude us from establishing requirements that kidney transplant centers must meet to participate in the Medicare program. In fact, the statute specifies that payment will be made for kidney transplantation to providers of services that ''meet such requirements as the Secretary shall by regulation prescribe * * *'' (See section 1881(b)(1)(A) of the Act.)

Further, as noted in the preamble to the proposed rule, we are committed to bringing both the kidney and extra-renal transplant requirements up to date. For consistency across all types of transplant centers, we are requiring Medicare-approved transplant centers, including kidney transplant centers, to submit transplant data per OPTN data submission requirements. No changes were made based on this comment.

Comment: Another commenter recommended that we amend the regulation text to require the submission of 95 percent of a program's data within 3 months of the due date and 100 percent of the program's data within 6 months of the due date.

Response: We expect transplant centers to comply with the OPTN policy to submit 100 percent of the required data within 6 months of the due date. However, we are not including the requirement in this final rule because a requirement for 100 percent compliance would be problematic within our framework for Medicare oversight and enforcement. For example, if the OPTN notified us that a transplant center had submitted only 99.9 percent of its data within the required time frame, under such a requirement we would consider the transplant center to be out of compliance, which could subject the transplant center to review and adverse action.

Clinical Experience

We requested comments on: (1) Whether requiring a minimum number of 9 transplants during a 2.5 year period would be acceptable for the application of the SRTR methodology; and (2) whether our proposal to focus more heavily on a center's outcomes by eliminating volume as a separate standard and integrating volume into our outcome measures would provide us with the necessary data. In addition, three peer reviewers provided comments on the following specific issues related to volume: (1) Other alternative minimum volume criteria that would ensure that the 3 test criteria can be applied properly; and (2) appropriateness of volume standards for pediatric transplants.

Comment: Only one commenter said that eliminating volume as a separate standard would be a positive change. Overall, commenters said that the proposed methodology-based volume of 9 transplants in a 2.5 year cohort would be unacceptable as a basis for approval or re-approval of transplant centers. Commenters noted that a threshold of 9 transplants in 2.5 years would be much lower than the current Medicare annual thresholds (10 for lungs and intestines, 12 for hearts and livers, and 15 for kidneys). One commenter said that the proposed volume should not be used to assess a center's performance because it neither serves the best interests of patients nor supports our stated goal to raise transplant standards. Another commenter said that no center performing only 9 transplants in 2.5 years can be considered a legitimate transplant program. Still another commenter said that the proposed volume is so low that it essentially would eliminate a requirement for volume. One commenter suggested that with the exception of isolated geographic locations, we should require 15 transplants as the absolute minimum annual volume, with a higher annual requirement for kidney and liver transplants, such as 30 transplants of each organ per year.

Two peer reviewers voiced concern that the methodology-based volume requirement we proposed may allow Medicare-approved centers to become inactive but retain their Medicare approval.

Response: We proposed requiring only 9 transplants in the 2.5 year cohort used for SRTR center-specific reports because 9 transplants is the minimum number necessary for the SRTR-based methodology to flag a poorly-performing center. In the preamble to the proposed rule, we acknowledged the possibility that a center could perform 9 transplants in a short period of time and remain inactive for a much longer period, while still retaining its Medicare approval. Nevertheless, we posited that the OPTN's oversight of transplant center ''functional inactivity'' would guard against this circumstance.

Additionally, in our move toward an outcome-focused system that reflects the clinical experience, resources, and commitment of a transplant program, we have revised the preamble and the regulations text by removing references to ''volume requirements'' and instead refer to ''clinical experience requirements.'' We believe this change reflects our intent to approve transplant centers using an outcome-based methodology under which the number of transplants performed is one of several factors we consider.

However, the comments we received from the public and from peer reviewers, as well as recent findings of prolonged inactivity or sub-optimal clinical experience at some transplant centers, have caused us to re-evaluate our position. In analyzing this issue, we considered several factors, including the possible impact of clinical experience on quality of outcomes and the ability of a patient on a transplant center's waiting list to obtain a transplant.

Few research studies have been conducted on the link between volume and quality of outcomes in transplantation. A 1994 study found a significantly higher 1-year post-transplant mortality rate among patients transplanted at centers that performed fewer than 9 heart transplants per year when compared to patients transplanted at centers that performed 9 or more heart transplants per year. (Hosenpud JD, Breen TJ, et al. The effect of transplant center volume on cardiac transplant outcomes: a report of the United Network for Organ Sharing Registry. *Journal of the American Medical Association*, 1994; 271: 1844–1849.)

A 1999 study using 1994 through 1997 data showed a similar correlation between liver transplant volumes and outcomes. Specifically, patients transplanted at liver centers that performed 20 or fewer transplants per year had significantly higher 1-year post-transplant mortality than patients transplanted at liver centers that performed more than 20 transplants per year. (Edwards, EB, Roberts JP, et al. The effect of the volume of procedures at transplantation centers on mortality after liver transplantation. *New England Journal of Medicine*, 1999; 341: 2049–2053.)

However, we believe it would be problematic to base clinical experience requirements on research conducted on transplants performed when survival rates, particularly liver transplant

survival rates, were significantly lower than they are today. That is, 1-year risk-adjusted survival after heart transplantation was 83.4 percent in 1994 but had increased to 87.96 percent during the most recent SRTR cohort for which data are available, July 1, 2002 through December 31, 2004. Further, 1-year risk-adjusted survival after liver transplantation was 76.3 percent in 1994 but had increased to 86.59 percent during the most recent time period for which data are available, January 1, 2003 through June 30, 2005. In contrast, 1-year survival from 1994 through 1997 at the high-volume liver centers in the 1999 study was only 80 percent.

A study published in 2004 looked at data for adult patients who received kidney or liver transplants between January 1, 1996 and December 31, 2000. (Axelrod DA, Guidinger MK, et al. Association of center volume with outcome after liver and kidney transplantation. *American Journal of Transplantation*, 2004; 4: 920–927.) The study found a significantly lower rate of 1-year post-transplant kidney graft failure at high volume centers when compared to medium, low, or very low volume centers. The study also found a significantly different rate of 1-year post-transplant patient mortality at high, medium, and low volume liver centers; low volume centers were associated with a significantly higher risk of death. Despite these findings, the study's authors concluded that there is no clear minimal threshold volume.

Additionally, the study's authors identified several potential implications from the results of the study, noting that efforts are underway in other (non-transplant) surgical fields to concentrate procedures at high volume centers when there is a relationship between volumes and outcomes. The study suggested that even with a clear association between volume and outcomes in transplantation, ''The adoption of such a policy for liver and kidney transplantation would not be straightforward even if it were desirable, particularly in the case of deceased donor transplantation [because] the benefit of high-volume center performance must be carefully weighed against the increased risk of graft loss associated with the increased cold ischemia time [that] would likely accompany increased regionalization of transplant services.'' The authors also pointed out that ''the frequent follow-up visits necessary after transplantation might prove to be an added hardship if patients were forced to travel great distances. Because patients may be more compliant with follow-up visits if appointments are convenient, compliance may also be an important determinant of outcome.''

Because research on the effect of volume on outcomes in transplantation provides little guidance in establishing the appropriate amount of clinical experience for Medicare approval, we looked at the waiting lists at heart, liver, and kidney centers that have volumes below current Medicare requirements, (12 transplants per year for heart centers and liver centers and 15 transplants per year for kidney centers), and compared them to the waiting lists at higher volume heart, liver, and kidney centers. We found indications that there may be a link between clinical experience and how well patients fare while they are still on the waiting list.

For example, in 2005, there were approximately 117 adult heart transplant centers in the United States. According to the SRTR, 69 centers performed 12 or more transplants, and 48 performed fewer than 12 transplants. Out of the 69 centers that performed 12 or more transplants, 1 had a higher than expected mortality on the waiting list. Of the 48 centers that performed fewer than 12 transplants, 5 had higher than expected mortality on the waiting list.

Nationwide in 2005, there were approximately 106 adult liver transplant centers in the United States. There were 6,122 patients on the liver transplant waiting list. Slightly more than 28 percent (1,745) of these patients died without receiving a transplant. Of the 96 adult liver transplant centers that performed 12 or more transplants in 2005, only one center had more deaths on the waiting list than the number of transplants it performed. However, among the 10 liver centers that performed fewer than 12 transplants in 2005, 5 centers had more deaths on the waiting list than the number of transplants it performed. Of those 5 centers, 2 centers had approximately 3 times the number of deaths on the waiting list as the number of transplants they performed. For example, one liver center performed 7 transplants in 2005 and had 20 waiting list deaths during the same time period.

We also considered whether center clinical experience affects the ability of waiting list patients to obtain a transplant by reviewing transplant rates for kidney centers in 2004/2005. The SRTR calculates whether a center's transplant rate for deceased donor transplants is statistically higher, statistically lower, or not significantly different from other transplant centers. Although we found no definitive link between a kidney center's clinical experience and the transplant rate calculated by the SRTR, we note that the transplant rate of a small center generally would not be considered statistically lower than expected even if the center performed no transplants during a given year due to the small number of patients on its waiting list. However, in reviewing the data, we found that 7 out of the approximately 231 adult kidney transplant centers in the United States in 2004 and 2005 performed no transplants at all during those 2 years. The number of patients on the waiting lists of the 7 centers numbered between 9 and 47. Although the number of patients affected was small, we are concerned that patients continued to be listed on the waiting lists of centers that performed no transplants in 2 years. We note that, at present, all 7 centers are listed as inactive on the SRTR's Web site.

In summary, public commenters and some peer reviewers recommended a volume standard higher than the proposed 9 transplants in 2.5 years. None of the peer reviewers recommended a specific volume. Studies of the effect of volume on outcomes in transplantation suggest that higher volume centers have better outcomes, although there is no evidence that indicates what the minimum threshold should be. Also, our review of waiting list data raises the concern that waiting list patients at small centers may not fare as well as waiting list patients at larger centers, both in terms of waiting list mortality and the ability to obtain a transplant.

Further, as discussed earlier in this preamble, in the fall of 2005, we found that some centers, although not considered ''functionally inactive'' by the OPTN, performed few transplants and refused a high percentage of organs that were offered to them for transplantation into their waiting list patients, leading to longer than average waiting times and, possibly, an increased number of deaths among their waiting list patients. These factors must be weighed against the necessity to maintain Medicare beneficiaries' access to transplantation. Also, we must keep in mind the concerns raised by the 2004 study of volume and outcomes in kidney and liver transplantation that centralizing transplants in too few centers could be detrimental to transplant outcomes.

Based on these considerations, we believe transplant centers should be required to perform more than 9 transplants in 2.5 years to become Medicare approved and, once approved, retain their Medicare approval. Without strong statistical evidence supporting a particular threshold for any of the organ types, we believe the most appropriate

solution is to establish a clinical experience requirement that is close to the current volume requirements in our NCDs for heart, intestine, liver, and lung transplant centers and in our CfCs for kidney transplant centers. We believe establishing a clinical experience requirement of 10 transplants per year for all organ types for both approval and re-approval of transplant centers is both sensible and the least disruptive for transplant centers that have current Medicare approval and for the beneficiaries on the waiting lists of these centers.

We are revising § 482.80(b) to state that to be Medicare approved under this final rule, adult transplant centers (with the exception of heart-lung centers, kidney transplant centers, and pancreas centers) generally must perform 10 transplants over a 12 month period. We are revising § 482.82(b) to state that to be re-approved under this final rule, a transplant center must perform an average of 10 transplants per year during the re-approval period. There are no minimum clinical experience requirements for initial approval or re-approval for heart-lung, pancreas, or pediatric centers. (Kidney transplant centers generally must perform 3 transplants over a 12-month period for initial approval and 10 transplants annually for re-approval.) (See §§ 482.80(d)(4) and 482.82(d)(4).) Note that an adult transplant center may not attempt to meet the clinical experience requirement by combining adult transplants with pediatric transplants performed at an affiliated pediatric center.

As stated previously, the main intent of the clinical experience requirement for re-approval is to ensure that Medicare-approved centers stay active. We recognize that a center's transplant numbers may fluctuate at times. Nonetheless, we believe that a transplant center must perform an average of 10 or more transplants per year to demonstrate commitment to its transplant program and gain adequate clinical experience.

To determine a center's compliance with the clinical experience requirement, we will review the data contained in the most recent OPTN Data Report and SRTR center-specific reports. (See § 488.61(a)(2) and § 488.61(c)(1)(ii).)

Comment: Some commenters said that all kidney transplant centers should be exempt from initial approval requirements (such as the requirement to perform 9 transplants) because a lengthy initial approval process would delay access to the new kidney center's transplantation services for Medicare beneficiaries. That is, until a new kidney transplant center receives Medicare approval, Medicare will not pay for beneficiaries to receive transplants at the facility.

Response: We share the commenters' concern that a lengthy approval process for kidney centers, particularly a requirement to perform 10 transplants prior to approval, may prevent kidney transplant centers from opening in areas of the country where access to kidney transplant services is already limited.[1] Meeting a clinical experience requirement of 10 transplants would be particularly difficult for new kidney transplant centers, because Medicare is either primary payer or secondary payer for 69 percent of kidney transplants performed in the United States, while the other 31 percent of kidney transplants are paid for by private insurance, Medicaid, and the Department of Veterans Affairs (unlike extra-renal transplants for which Medicare pays between approximately 20 percent and 40 percent, depending upon organ type). Thus, a new kidney transplant center would have considerable difficulty finding 10 non-Medicare patients to transplant.

Under the current ESRD CfCs for kidney transplant centers, a new center may be approved without performing any transplants if it has a written plan detailing how it will achieve conditional status (7–14 transplants) within 2 years and unconditional status (15 or more transplants) within 4 years. Currently, there are no outcome requirements for kidney transplant centers. However, this final rule contains outcome requirements for initial approval of kidney transplant centers, and in order for us to assess a new kidney transplant center's performance, the center must perform some transplants. Taking this information into consideration, we have determined that requiring new kidney transplant programs to complete 10 transplants before applying for approval could prevent new centers from entering the Medicare program.

We believe that completing 3 consecutive, successful transplants, as determined by 1-year post-transplant graft and patient survival outcomes, is necessary for a new kidney center to demonstrate sufficient experience in transplantation and enhances the new transplant center's ability to recruit transplant candidates from the limited pool of the non Medicare-eligible kidney transplant candidate population.

We are sensitive to the difficulty a new kidney transplant center will have in finding non-Medicare patients to transplant. We are committed to maintaining and improving access to kidney transplantation services for Medicare beneficiaries, but we also believe it is essential to assess a kidney transplant center's performance prior to approving it for the Medicare program. Therefore, this final rule establishes a clinical experience requirement of 3 transplants for initial Medicare approval for kidney transplant centers that had not been approved by Medicare under § 405.2122 as of this rule's effective date at § 482.80(d)(5). We believe this requirement will allow new kidney transplant centers to obtain Medicare approval expeditiously, while ensuring that some data are available to demonstrate whether the center's outcomes are acceptable.

Like extra-renal transplant centers, kidney transplant centers will be approved for 3 years and will be required to perform an average of 10 transplants per year for re-approval. However, because a kidney center will be required to perform only 3 transplants before obtaining initial approval, we will scrutinize the center's clinical experiences and outcomes closely, particularly in the year following its initial approval. CMS will monitor the clinical experience and outcomes statistics of the center in the year following its initial approval. We are requesting center-specific data already collected through the OPTN, and expect to review the data at least quarterly. If the center's clinical experience and outcomes highlight a need for additional investigation, CMS will follow up through its survey and certification process.

We note that in the past, new transplant centers interested in applying for Medicare approval have offered to perform transplants for Medicare beneficiaries free of charge so that the center could meet the clinical experience requirement for initial Medicare approval quickly. This practice has serious implications for a Medicare beneficiary who accepts a transplant center's offer of a free transplant. Medicare pays for prescription drugs used in immunosuppressive therapy under Medicare Part B only if the transplant was performed in a Medicare approved facility. Although an individual may be eligible for payment for his or her immunosuppressive drugs under

[1] Although nearly half of all transplant centers in the United States are kidney transplant centers, there are barriers to access to kidney transplantation services in some areas of the country where there are large dialysis populations but few kidney transplant centers, and in some largely rural States that have no in-State kidney transplant centers and few centers in neighboring States.

Medicare Part D, the beneficiary may pay several thousand dollars more out of pocket every year.

Therefore, we have added a requirement under the CoP for Patients' and Living Donor Rights at § 482.102(a)(8) and (b)(9) that a transplant center must inform Medicare beneficiaries who are prospective transplant recipients and their prospective living donors that receiving a transplant that is not provided in a Medicare-approved transplant center could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid under Medicare Part B. See further discussion of this requirement in this preamble under ''Patients and Living Donor Rights'' and ''Centers With Current Medicare Approval.''

Comment: A commenter stated that OPTN policies do not specify that transplant centers must perform a minimum number of transplants per year and said that our requirements and those of the OPTN should be consistent. A commenter also asked us to clarify in more detail what the OPTN means when it terms a transplant center ''functionally inactive,'' as well as how this status may impact a center's eligibility to receive organs.

Response: As discussed in the proposed rule, although the OPTN does not require a transplant center to perform a minimum number of transplants, programs (centers) are reviewed and may be classified as ''functionally inactive'' if they have not performed a single transplant within a specified period of time. The specific time frame that the OPTN Membership and Professional Standards Committee (MPSC) uses to determine ''functional inactivity'' is 3 months for kidney, liver, and heart programs, 6 months for pancreas and lung programs, and 1 year for stand-alone pediatric programs. Under OPTN Bylaws, Appendix B(II), an OPTN member transplant hospital that fails to remain functionally active with respect to any designated transplant program may be encouraged to voluntarily deactivate its transplant program until such time as the circumstances affecting the status of the program have been resolved (up to 12 months) or relinquish designated transplant status for the program. If the member fails to take either action voluntarily, the MPSC may recommend that the Board of Directors notify the Secretary of this inactivity (if the transplant program is Medicare approved or located within a Federal hospital) and take appropriate action in accordance with the OPTN bylaws.

The OPTN's determination that a transplant program is ''functionally inactive'' does not, by itself, prohibit a center from receiving organs. However, hospitals with transplant centers usually follow the recommendation of the MPSC by voluntarily inactivating the transplant center in question.

Although we want to ensure that transplant centers remain active, we do not want a transplant center that is experiencing problems to continue to perform transplants just to avoid losing its Medicare approval. Therefore, we have added a provision to this final rule that a transplant center may inactivate its program for a period not to exceed 12 months during the 3-year approval cycle without losing its Medicare approval (see § 488.61(e)), but the center must notify us immediately of significant changes in the number of transplants performed, as required at § 482.74(a)(4). The transplant center also must notify the patients on its waiting list and, as requested by the Secretary, assist patients in transferring to the waiting list at another transplant center, without loss of time accrued on the waiting list. (See § 482.102(c)(3).) We will confer with HRSA and the OPTN on a case-by-case basis to determine whether to instruct an inactive center to notify its waiting list patients and assist them in transferring to another transplant center's waiting list.

We proposed that a center that was requesting initial Medicare approval to perform pediatric transplants would not be required to perform a minimum number of pediatric transplants prior to its request for Medicare approval.

Comment: Most commenters agreed that volume requirements are not relevant for pediatric centers and they strongly supported having no volume requirements for centers performing pediatric transplants. Two peer reviewers said that a volume requirement would be inappropriate for pediatric centers. One peer reviewer agreed that volume standards are not appropriate for pediatric transplant programs, but also expressed concerns about the ability of pediatric centers to maintain their expertise because many centers perform so few pediatric transplants. Another peer reviewer stated that since setting a volume requirement for small pediatric centers is challenging, Medicare approval for pediatric centers that are affiliated with Medicare-approved adult transplant programs is recommended. Like the other peer reviewer, this peer reviewer also had concerns about small, stand-alone pediatric transplant programs' ability to maintain resources and expertise in transplantation.

However, two commenters stated that a minimum volume requirement is necessary to ascertain the commitment and investment a hospital has made in its pediatric transplant center. One commenter recommended ten pediatric transplants a year for liver and kidney programs and a lower volume for heart programs. The commenter suggested counting open and closed congenital heart surgeries toward the volume requirement for pediatric heart transplants. One commenter expressed a strong belief that having no volume requirement for pediatric transplant centers would allow small programs with limited resources to perform transplants, with potential poor outcomes.

Response: Given the nature of the pediatric transplants performed and the low numbers of pediatric transplants in general, it would be impossible for most pediatric transplant centers to obtain Medicare approval if we required them to meet clinical experience requirements, limiting access for pediatric Medicare beneficiaries who need transplants. As stated earlier, we will monitor pediatric centers' outcomes to ensure they provide high quality transplantation services to Medicare pediatric patients. We made no changes based on this comment.

Comment: Some commenters stated that in most pediatric centers, the core transplant team performs both adult and pediatric transplants. The commenters said that to be consistent with OPTN requirements for pediatric centers, we should allow the sharing of personnel in transplant hospitals that have both adult and pediatric transplant programs. Some commenters recommended treating adult and pediatric transplant centers as one unified program or adopting the pediatric heart transplant center statutory approval criteria.

Response: We recognize that many centers that perform pediatric transplants are operated by or affiliated with a Medicare-approved adult transplant center. In some transplant centers, the core transplant team performs both adult and pediatric transplants. We have no objection to such arrangements, provided that a transplant center has committed sufficient resources to both its pediatric and its adult transplant programs. There is nothing in the final rule that precludes a pediatric center and an adult center from operating as one unified program. Nonetheless, approval of the pediatric center is not automatic. The pediatric center and adult center must apply for separate approval.

We invited comments from the public on the proposed outcome requirements.

In addition, we conducted independent peer reviews of the following specific issues related to the outcome requirements:

(1) Appropriateness and usefulness of using 1-year post-transplant graft and patient survival rates to assess transplant center performance;

(2) Alternative outcome measures;

(3) Appropriateness of using 1-month post-transplant data for initial approval of new centers;

(4) Outcome measures for heart-lung, intestine and pancreas transplant centers;

(5) Use of the Cox model to explain the risk-adjusted expected 1-year post-transplant graft and patient survival rates;

(6) Appropriateness of using the 3 proposed thresholds to determine center performance; and

(7) Use of the proposed p-value to assess centers with ≥ 9 transplants during a 2.5-year period. None of the peer reviewers suggested alternative outcome measures. All reviewers agreed that the Cox model is the most widely used, flexible, and reliable tool to measure transplant outcomes because it allows adjustments, additions, or deletions of co-variables to reflect clinical changes in transplantation over time.

Following are summaries of the comments we received and our responses.

Use of 1-Year Post-Transplant Graft and Patient Survival Rates as Outcome Measure Standards

In our discussion of outcome measures in the preamble to the proposed rule, we said that we would compare each transplant center's observed number of patient deaths and graft failures 1-year post-transplant to the center's expected number of patient deaths and graft failures 1-year post-transplant, using the most recent SRTR center-specific reports. We also stated that we would not consider a center's patient and graft survival rates to be acceptable if a center's observed patient survival rate and observed graft survival rate is lower than its expected patient survival rate or expected graft survival rate.

Comment: Many commenters agreed that risk-adjusted graft and patient survival rates are appropriate measures of transplant center performance. Some commenters stated that the proposed comparison of 1-year observed graft/patient survival rates with 1-year expected graft/patient survival rates is reasonable and achievable. The commenters noted that the proposed risk-adjusted survival data with a 1-year follow-up period has more statistical validity than the evaluation of a survival curve at a particular time point, such as when the Kaplan Meier model is used. The commenters appreciated our effort to strive for consistency with OPTN standards and in establishing meaningful outcome standards. One commenter believed that outcome measure reviews should be based on trends and not just on one single snapshot in the SRTR reports.

All three peer reviewers agreed with the public commenters that it is appropriate to use 1-year graft and patient survival rates to assess transplant center performance. Three peer reviewers added that a survival time frame longer than 1 year, such as 3 years or 5 years, may provide a more accurate assessment of center performance and minimize statistical deviations for small centers. However, they pointed out that the drawback of a longer time frame is that more patients would be lost to follow up, and a longer time frame may not be applicable to smaller programs.

Response: Although we agree that a time frame for the outcome measures longer than 1-year post-transplant would provide some additional information, the drawbacks include increased mortality from patients' co-morbidities and more patients lost to follow up. We believe that utilizing 1-year survival data for approvals and re-approvals is sufficient. We have made no changes based on these comments.

Alternatives to the OPTN Outcome Thresholds

We solicited comments on different options to apply the SRTR methodology. Following are summaries of the comments we received and our responses.

Comment: A commenter stated that graft and patient survival rates alone do not give a complete picture of transplant center performance. The commenter encouraged us to continue to identify or develop measures to capture the full scope of a transplant center's performance.

Response: We agree with the commenter that graft and patient survival rates alone do not provide a complete picture of transplant center performance. To provide a broader view, we will assess each center's compliance with the other CoPs, which focus on other measures of quality, such as direct patient care. If the OPTN and SRTR develop additional measures, we will consider whether those measures should be incorporated into our CoPs through the rulemaking process. We made no changes based on this comment.

Comment: A commenter suggested including waiting list mortality, the number of organ donors, and the size of the waiting list in the outcome measure analysis.

Response: We considered using waiting list mortality as one of the outcome measures, but after careful deliberation, we determined that using this criterion would be problematic because transplant centers do not provide direct patient care for all of the patients on their waiting lists. Some waiting list patients routinely receive their primary care from other providers, particularly patients awaiting kidney transplants who are likely to receive their care through a dialysis facility. In addition, some waiting list patients are listed at more than one center. We would have considerable difficulty determining which transplant center should be accountable for the death of a patient listed on more than one waiting list. Finally, waiting list patients may die for reasons unrelated to their end-stage organ failure. We believe it would be unfair to hold a transplant center responsible for the death of a waiting list patient if the cause of death were unrelated to the patient's transplant.

Although the commenter suggests using the number of organ donors as one of the outcome measures in the final rule, we would point out that cooperating with organ procurement organizations (OPOs) in the organ donation process would be a function of the hospital in which a transplant center is located, not of the transplant center itself. Furthermore, the hospital CoP at § 482.45 ''Organ, tissue, and eye procurement'' lists specific requirements all hospitals must meet related to their performance as donor hospitals. We made no changes based on this comment

Comment: A commenter also suggested using the size of a transplant center's waiting list as an outcome measure.

Response: We disagree. There are many different variables affecting the size of a transplant center's waiting list, such as geographic location, patient selection criteria, cultural factors, and transplant resources, among others. Thus, we do not believe the size of a transplant center's waiting list is an appropriate outcome measure. We did not make any changes based on these comments.

The 3 Thresholds (p < 0.05, Observed—Expected > 3, and Observed/Expected > 1.5)

We requested comments on the three proposed non-compliance thresholds for the outcome measures and solicited data and evidence that would support alternative thresholds, especially thresholds specific to a particular organ type.

We proposed that a transplant center's performance would not be acceptable if its observed patient survival rate and observed graft survival rate were lower than its expected patient survival rate and expected graft survival rate and if all three of the following thresholds were crossed over:

(1) One-sided p-value is less than 0.05;

(2) Number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3; and

(3) Number of observed events divided by the number of expected events is greater than 1.5.

Comment: Although some commenters expressed support for the three proposed thresholds, a few commenters stated that these thresholds would be too lenient. Other commenters suggested making the thresholds more rigorous but only if the outcome measures were used solely as a trigger for further investigation. Three peer reviewers supported using all 3 proposed non-compliance thresholds (p < 0.05, O—E > 3, and O/E > 1.5) to determine transplant center performance. However, one peer reviewer recommended changing the threshold for O/E > 1.5 to O/E > 1.3 in order to narrow the variations among centers. One commenter stated that the three thresholds for outcome measures are arbitrary since the outcome measure methodology may change in the future.

Response: We disagree that the proposed thresholds are too lenient. The OPTN uses the same thresholds currently to flag centers for further review, and the SRTR uses the thresholds to report observed and expected patient and graft survival.

Changing the threshold of O/E > 1.5 to O/E > 1.3, as one peer reviewer suggested, would be inconsistent with the OPTN O/E threshold for flagging centers for further review. If the OPTN changes the criteria to narrow the variation in the future or we determine that the threshold is insufficiently rigorous for our purposes, we will re-assess it.

We will not use these thresholds simply to flag centers for further review as suggested by some of the commenters. Although failure to meet the outcome requirements does not mean that a transplant center will be denied Medicare approval automatically or lose Medicare approval automatically, a transplant center's performance on the outcome requirements is the single most important factor we will consider in making these determinations because these measures are designed to reflect the importance of the need for a transplant center to have sufficient expertise in all phases of transplantation, such as conducting pre-transplant evaluations, performing the surgical procedure, and regulating post-transplant immunosuppression and other medications to prevent graft failure. Since we will be using outcomes data, along with other data and information on transplant center performance, to make decisions on initial approvals and re-approvals of transplant centers, we believe the thresholds are sufficiently rigorous to ensure we can identify transplant centers whose performance is unacceptable.

We do not agree that simply because we or the OPTN may change the proposed outcome requirements in the future, they are definitionally arbitrary. We are establishing thresholds at a level that is optimal to identify transplant centers whose performance is not adequate for delivery of transplantation services to Medicare beneficiaries. If we determine in the future that any of the three thresholds is too low or too high, we will propose changes in the threshold through the rulemaking process. We made no changes based on these comments.

Comment: A few commenters suggested that we should establish the criteria for unacceptable performance at crossing over 2 out of the 3 (instead of all 3) non-compliance thresholds.

Response: Throughout the final rule, we have been careful to conform our requirements to OPTN policies in almost all cases, so that our requirements for and our oversight of transplant centers does not conflict with the OPTN's. Currently, the OPTN requires that a transplant center has crossed over all three thresholds to be flagged for further review. We do not believe it would make sense to adopt the SRTR methodology and most of the OPTN's outcome measures policies in this final rule but establish a different criterion for the thresholds. In addition, we are mindful that the existing OPTN thresholds were established with the support of the transplant community. If the OPTN changes its thresholds in the future, we will determine at that time whether we should change the thresholds in our regulations. We made no changes based on this comment.

Comment: A commenter pointed out that the OPTN uses a 2-year cohort, but we proposed using a 2.5-year cohort. Commenters said that use of different cohort lengths would lead to different results when centers are reviewed.

Response: As of 2005, the SRTR changed the OPTN cohort from 2 years to 2.5 years to be consistent with the public SRTR center-specific reports.

Appropriateness of Using the Proposed Outcome Requirements, the 3 Thresholds, and the SRTR Methodology as the Basis To Approve and Re-Approve Transplant Centers

Comment: A few commenters supported the basis for the outcome measure methodology designed by the SRTR and tested within the transplant community. Commenters said they believed that the proposal meets the principles of equity and fairness, and the outcome measures can be applied equitably to all types of transplant centers, both large and small. However, one commenter stated that the OPTN outcome data were never designed as a test for Medicare approval and re-approval. The commenter recommended that we defer any approval or re-approval decisions regarding data submission or outcome requirements to the OPTN Board, which makes the final decision about transplant center performance.

Response: We have been using patient survival outcome measures as approval criteria for transplant centers since Medicare began paying for heart transplants in 1987. Over the years, we have established outcome requirements for approval of liver, lung, and intestine transplant centers, as well. The sophisticated SRTR methodology described in this final rule allows us to improve upon the current outcome requirements by incorporating risk adjustment and ensuring statistical validity. Clearly, the outcome requirements that we are establishing in this final rule also can be utilized as indicators for potential problems, which is how we will use them in the approval and re-approval processes. Non-compliance with data submission, clinical experience, or outcome measure requirements may trigger a review for compliance with the CoPs, similar to the OPTN process, which also uses transplant outcomes data to flag centers for further review and investigation. However, as stated previously, the OPTN does not have the oversight authority to approve or re-approve transplant centers for Medicare. We

must conduct the review and investigation of a transplant center that does not meet the outcome measures. We have made no changes in this final rule based on this comment.

Comment: A few commenters stated that the SRTR center-specific report that we cited for review and approval/re-approval of transplant centers is 1 to 3 yrs behind current data and does not reflect a transplant center's current outcomes. Therefore, centers that have improved recently may be sanctioned unnecessarily. The commenters recommended that we review more recent data or data in at least two previous SRTR reports to evaluate a transplant center's outcome trends.

A peer reviewer stated that the outcome measure review should be based on outcome trends over a longer period of time and not on a single snapshot in the SRTR report. Another reviewer recommended a review of graft and patient survival rates in two consecutive SRTR reports.

Response: We agree that some transplant centers' outcome trends may be best understood by reviewing two SRTR reports. However, since our approach to approving centers is multi-dimensional (data, clinical experience, outcomes, and process), and the OPTN review of transplant centers is ongoing, we believe that review of one SRTR report is sufficient to assess a transplant center's performance. If we consistently use the SRTR center-specific reports for outcome review, the trend of a center's performance or a clinically significant pattern should be reasonably apparent over an extended period of time. The SRTR updates its center-specific reports every 6 months. However, since the outcome requirements in this rule include 1-year post-transplant data, the delay in compiling and reporting the data by the SRTR is unavoidable. Thus, the age of the data that we review will vary from 1.5 to 3 years old.

Nevertheless, the SRTR reports provide the most cost-effective, transparent, and objective measures currently available. Since we will use the SRTR center-specific reports consistently to review outcomes, the trend of a center's performance or a clinically significant pattern should be reasonably apparent over an extended period of time. An on-site survey will counterbalance the outcomes data if the outcome trend is negative but is not reflective of the center's performance. On the other hand, the reporting of significant (negative) changes and inactivity to CMS will counterbalance the outcomes data if the center's performance trend appears to be positive but is, in fact, not reflective of the center's performance.

Comment: Some commenters were concerned that the proposed outcomes requirement may not be able to accommodate future changes in the OPTN's policies for application of the SRTR methodology or the methodology itself. A commenter suggested that we should include provisions to assure automatic adoption of future changes in the OPTN/SRTR data submission and outcome measure policies through issuance of Program Notices.

Response: The SRTR refines their methodology on an ongoing basis. For example, the SRTR reassesses the methodology's risk adjustment factors periodically and makes changes based on research and changes in the field of transplantation. The SRTR also adds or changes data sources, as appropriate. Periodically, the OPTN asks the SRTR to look into statistical techniques to improve data analysis. Such changes will not require us to engage in rulemaking. If the OPTN makes a substantive change to its policies regarding the methodology or chooses a different methodology for calculation of outcomes, we will assess the change to determine whether we should adopt it. For example, if the OPTN were to change the threshold for the p-value, and we determined that the change to the threshold would be appropriate for our outcome requirements, we likely would be required to engage in rulemaking so that the public would have the opportunity to comment. Based on our knowledge of the OPTN's past practices, we do not expect substantive changes to occur frequently. In fact, since the OPTN published the first annual report containing transplant center-specific outcomes data and transplant survival rates in 1992, there has been only one major change in the methodology used to measure outcomes—the change from the OPTN methodology to the SRTR methodology, which took place in 2002. We have made no changes based on these comments.

Risk-Adjustment Factors

Comment: Many commenters expressed concern that the SRTR model does not include all the risk-adjustment factors impacting outcomes, for example, new immunosuppression protocols, organs from extended criteria donors (ECDs) and donors after cardiac death (DCDs), steatosis, and centers' participation in research. The commenters were concerned that: (1) Transplant centers may be penalized for using organs from ECDs and DCDs if using such organs leads to poorer outcomes; (2) centers may refuse to use such organs because they fear their outcomes will be affected; (3) centers may be penalized for participating in research studies that yield negative outcomes; and (4) some centers may deny access to high-risk patients in order to meet the outcome measures.

One peer reviewer also expressed concern that the SRTR model does not risk adjust for organs from DCD or ECD donors, which the reviewer said may need to be incorporated into the model to meet the needs of an increasingly aging recipient population.

Response: We understand the commenters' and the peer reviewers' concerns. However, the SRTR methodology is not simply a list of covariates or values for parameter estimates. The SRTR revises risk-adjustment factors periodically in response to trends in organ donation and transplantation. For example, it has already included ECD organs as one of the risk-adjustment factors in its outcome methodology model so that centers using ECD organs frequently are not disadvantaged. We are confident that the OPTN/SRTR will be able to develop appropriate risk-adjusted outcome measures for DCD donor organs in the future. We made no changes based on these comments.

Appropriateness of Allowing a New Center to Use 1-Month Post-Transplant Data and Frequency of Subsequent Review of the Center's Post-Transplant Data

We proposed that if a new transplant center hired an experienced team from another transplant center, we would permit the new center to request that we review its 1-month post-transplant patient and graft survival for all transplants performed in the previous 1-year period, if the following conditions were met: (1) The key members of the center's transplant team performed transplants at a Medicare-approved transplant center for a minimum of 1 year prior to the opening of the new center; (2) the transplant team met the human resources requirement at § 482.98; and (3) the most recent SRTR report on the center did not contain 1-year post-transplant follow-up data on at least 9 transplants of the appropriate organ type for the reported time frame.

We proposed that if we approved a transplant center based on 1-month post transplant outcomes data, we would re-evaluate the center when 1-year post-transplant data became available.

We asked for comments on our proposal, as well as comments regarding the frequency with which we should re-

assess these new centers after they receive initial Medicare approval.

Comment: Some commenters supported the idea of approving new centers based on 1-month post-transplant data. The three peer reviewers did not object to the proposal to review a new center's 1-month post-transplant graft and patient survival outcome; however, they believed that reviewing a new center's 3-month or 6-month post-transplant data would provide more relevant information. One peer reviewer recommended an interim approval of new centers based on a 1-month post-transplant data review, pending a subsequent review of 3-month post-transplant data. Another peer reviewer recommended the comparison of projected 1-year post-transplant graft and patient survival rates with the expected 1-year post-transplant graft and patient survival rates, in addition to review of 1-month post-transplant data.

Some commenters stated that 1-month post-transplant data may be more reflective of the transplant team's surgical outcomes than the quality of the transplant center. One peer reviewer suggested that 1-month post-transplant data is too close to the date of the transplant and, thus, patient outcomes may not truly reflect the impact of the transplantation itself. The peer reviewer recommended that a 3-month post-transplant data review, in conjunction with three consecutive annual reviews, is a better marker for new center approval.

Another peer reviewer stated that approval of new centers based on review of 1-month post-transplant data for approval of new centers would be ill-advised. The peer reviewer said that 1-month post transplant data likely reflect primarily surgical expertise and the quality and the thoroughness of pre-transplant evaluation, rather than the skill of the multi-disciplinary transplant team. The peer reviewer stated that the use of 1-month post-transplant data for approval of new centers should be allowed only when the new center has demonstrated acceptable 1-year post-transplant graft and patient survival rates in other established organ transplant programs. The peer reviewer said that having acceptable 1-year post-transplant graft and patient survival rates for a minimum of 9 transplants should be mandatory for a new center that has no other organ transplant experience. Some commenters stated that simply having an experienced surgeon or transplant team should not be sufficient to qualify a new center. One commenter said that there are other factors besides surgical or transplantation experience that we should use to assess a new transplant center's performance. Another commenter expressed concern that Medicare approval of new centers based on review of 1-month post-transplant data would:

(1) Create an incentive for transplant teams to move from center to center, thus causing disruption to transplant patient services, negatively impacting patient follow up, significantly undermining the financial and human resource investment of transplant centers, and increasing costs to the health care system; and

(2) Raise patient safety issues, because experience indicates that it takes more than a year for a transplant center to develop and maintain a comprehensive transplant program.

Response: The comments from peer reviewers and the public, as well as the recent, abrupt closure of a new kidney transplant center following an investigation by the California Department of Managed Health Care, have led us to the conclusion that approving new transplant centers based on a review of 1-month post-transplant outcomes data and the experience of the transplant surgeon and transplant physician would not serve the best interests of Medicare beneficiaries who need transplants.

We share the commenter's concern that approving transplant centers based on 1-month post-transplant data has the potential to harm patient care. Most important, we have been unable to identify a need for centers to be approved quickly using abbreviated data.

Establishing a new transplant center is not an easy task. Clearly, a transplant center must provide non-surgical support services for transplant patients and perform many functions in addition to the transplant surgery itself, including, but not limited to, nursing, nutrition counseling, social services, pharmacology, immunology, pathology, and radiology. In fact, the president of the managed care organization that recently shut down its new kidney center was quoted as saying that establishing a transplant program was much more difficult than anticipated and that the organization was naïve to think the program could be established quickly.

Furthermore, we believe it would be inadvisable to approve a new center based on the fact that the hospital in which the center is located has a successful center that transplants another type of organ, as one commenter recommended (unless there is a direct relationship between organ types, such as a kidney center that seeks approval as a pancreas center). The SRTR center-specific reports indicate that the performance of organ transplant centers is not always consistent within a multi-center transplant hospital. Within the same transplant hospital, some centers may have outstanding outcomes while some centers may have marginal or sub-optimal outcomes.

Taking these factors into consideration, we believe it would be inappropriate for us to use the expertise of the key members of a transplant center's team as a proxy for the quality of a transplant center's overall operations.

Consequently, we have eliminated proposed § 482.80(b)(4) through (6). Under this final rule, we will use 1-year post-transplant patient and graft survival data to assess the performance of all transplant centers seeking initial Medicare approval.

Outcome Requirements for Heart-Lung, Intestine, and Pancreas Centers

We requested comments on the appropriateness of having no outcome requirements for heart-lung, intestine, and pancreas centers. We also asked for recommendations for alternative methods to evaluate centers that transplant these types of organs.

We proposed defining a heart-lung transplant center as a center that is located in a hospital with an existing Medicare-approved heart transplant center and an existing Medicare-approved lung transplant center that performs combined heart-lung transplants. We proposed defining an intestine transplant center as a Medicare-approved liver transplant center that performs intestine transplants, combined liver-intestine transplants, or multivisceral transplants. We proposed defining a pancreas transplant center as a Medicare-approved kidney transplant center that performs pancreas transplants alone or subsequent to a kidney transplant, as well as kidney-pancreas transplants. That is, we proposed that a Medicare-approved kidney transplant center would be permitted to perform all types of pancreas transplants.

Comment: Some public commenters supported having no outcome measure requirements for heart-lung, intestine, and pancreas transplant centers since there are no risk-adjusted outcome measure models for these types of transplants. Three peer reviewers agreed with our proposal for heart-lung, intestine, and pancreas centers but added that once a risk-adjusted outcome measure model becomes available in the

future, it should be applied to these centers.

Response: Once the SRTR has developed risk-adjusted models for heart-lung transplants, intestine transplants, and pancreas transplants, we will consider establishing outcome measure criteria for the approval and re-approval of centers that perform these transplants.

In the absence of risk-adjusted outcome measure models for these types of organ transplants, we believe the approach we proposed and have made final in this rule without change is most appropriate at this time.

Outcome Measures for Pediatric Transplants

We requested comments on our proposed approach to evaluating pediatric transplant centers' outcomes and approving centers performing pediatric transplants.

Comment: Some peer reviewers were concerned about pediatric centers' ability to maintain resources due to infrequent transplantation activities. A reviewer stated that the OPTN routinely peer reviews pediatric program case logs, and the peer reviewer recommended that the OPTN notify us about under-performing programs using pre-established thresholds.

One commenter agreed with our proposal to apply outcome requirements for adult centers to centers performing pediatric transplants. However, one commenter voiced concern that the inability of pediatric centers to perform 9 transplants in a 2.5-year period (as required for the SRTR methodology to be valid) may prevent them from participating in Medicare. Nonetheless, the commenter urged the SRTR to continue analyzing pediatric 1-year post-transplant outcomes. The commenter encouraged the SRTR to develop evidence-based outcome guidelines by analyzing center-specific 1-year outcomes of pediatric patients transplanted over a 2.5-year period.

Response: We intend to confer with the OPTN, as appropriate, about both pediatric and adult centers to ensure that we can effectively monitor the quality of transplant programs.

Proposed Process Requirements for Transplant Centers

Condition of Participation: Patient and Living Donor Selection (Proposed § 482.90)

We proposed requiring centers to use written patient selection criteria in determining a patient's suitability for placement on the waiting list for transplantation. We proposed that patient selection criteria must ensure fair and non-discriminatory distribution of organs.

We proposed that before a patient is selected for a non-renal transplant, the transplant center must consider or employ all other appropriate medical and surgical therapies that might be expected to yield both short and long-term survival comparable to transplantation.

We proposed that before a center places a patient on its waiting list, the center must ensure that the prospective transplant candidate receives a psychosocial evaluation and that the potential transplant candidate's medical record contains documentation of the candidate's blood type. (A psychosocial evaluation conducted by transplant centers of potential transplant recipients screens for issues that could affect the patient's compliance with the post-transplant treatment that is necessary to maximize the chances of a successful transplant, such as substance abuse or behavioral or psychiatric issues.) We also proposed that when a patient is placed on a center's waiting list, the center must document in the patient's medical record the patient selection criteria used.

We proposed that if a center performs living donor transplants, the center must use written donor selection criteria in determining the suitability of living donors for donation. We proposed that the living donor selection criteria must be consistent with the general principles of medical ethics. We proposed that the transplant center must: (1) Ensure that a prospective living donor receives a medical and psychosocial evaluation prior to donation; (2) document in the transplant candidate's and living donor's medical records the living donor's suitability for donation; and (3) document that the living donor has given informed consent, as required under § 482.102. The psychosocial evaluation conducted by a transplant center of a potential living donor assesses the donor's motivation and his or her understanding of the donation process and post-donation treatment. A center assesses whether the potential living donor has any behavioral or psychiatric issues that could influence the decision to donate and whether he or she is being pressured to donate.

Following are summaries of the comments we received and our responses.

Comment: Many commenters supported the proposed written patient and living donor selection requirements. Commenters stated that the requirements are reasonable and that many centers already have these selection criteria in place. One commenter applauded us for giving transplant centers the flexibility to develop their own criteria. The commenter commended us for refraining from defining patient selection criteria. However, some commenters opposed the requirement for transplant centers to have written patient and living donor selection criteria. Commenters stated that the requirements are too prescriptive and would be burdensome.

Response: We disagree that these requirements are too prescriptive. In fact, current Medicare requirements for heart, liver, and lung transplant centers have specific patient selection criteria guidelines for centers to use to select patients for transplantation. Conversely, this final rule permits transplant centers to develop the criteria that best fit the needs of their patients and gives centers the flexibility to change their criteria as transplant medicine changes over time. We will no longer require transplant centers to use the existing patient selection criteria. As long as their patient selection criteria are fair and non-discriminatory, transplant centers are free to develop their criteria based on the medical judgment of their transplant physicians and surgeons.

Comment: Some commenters said they believe that written patient selection criteria may pose undue risk to centers when the criteria used to select a transplant patient deviate from the transplant center's written criteria. Another commenter stated that the disclosure of deviations from patient selection criteria will pose legal risks for transplant centers.

Response: We disagree with the commenters that written patient and living donor selection criteria will pose undue legal risk to centers. Instead, we believe that well-written patient and living donor selection criteria can reduce the legal risk for a transplant center, as long as the center adheres to its criteria or documents the reason why it has deviated from its criteria. Given the scarcity of organs, we believe established written patient selection criteria, at a minimum, will ensure equity and consistency when transplant risk-benefit decisions are made. No change was made based on these comments.

Comment: Some commenters stated that patient selection is a medical judgment and that there are gray areas, subtleties, and subjectivities involved in selecting patients for transplants.

Response: We acknowledge that selecting patients for transplantation is the responsibility of the transplant surgeon and that transplant surgeons

must exercise their medical judgment when weighing the risks and benefits of transplantation. This final rule does not dictate how transplant candidates should be selected for placement on the waiting list and transplantation. Although we require transplant centers to have written patient selection criteria, transplant centers are free to include a process for justifying exceptions to the selection criteria.

Comment: A few commenters stated that the proposed requirement for written patient criteria is duplicative of the OPTN patient listing policies. The commenters said that a center's adherence to the OPTN policies should satisfy our patient selection criteria.

Response: The OPTN policies for patient placement on the waiting list focus mainly on the criteria for organ allocation and not on the criteria for placement on or exclusion from a center's waiting list. We believe that if transplant centers adhere to OPTN policies and comply with the patient selection criteria requirement in this final rule, they will place patients on their waiting lists appropriately. Therefore, we have finalized the patient selection criteria requirement as proposed.

Comment: A commenter stated that patient selection for transplants is usually a medical judgment based on guidelines developed by professionals. Guidelines change from time to time. A commenter recommended the Patient Care and Education Guidelines developed by the American Society of Transplantation as a helpful resource for transplant decisions.

Response: We support the concept of incorporating professional guidelines into a transplant center's transplant candidate selection policies, as the center deems appropriate. We expect that transplant centers will revise their policies periodically as needed. We have made no changes based on this comment.

Comment: A commenter stated that we should encourage patients to take some responsibility for their own care. The commenter suggested that in the transplant candidate evaluation process provision, we should include some patient self-management provisions.

Response: We agree with the commenter that transplant candidates should share responsibility for their own care. Transplant centers are free to incorporate this concept in their patient evaluation policies. However, including such a requirement in regulations would be unnecessarily prescriptive.

Comment: Some commenters opposed the requirement that a transplant center must employ or consider all other appropriate medical and surgical therapies that might be expected to yield both short and long-term survival comparable to transplantation before a patient is selected for placement on the waiting list. The commenters said this practice interferes with medical judgment and may place transplant centers at legal risk. A few commenters requested an exemption for kidney, heart, and pancreas transplant centers from this requirement because transplant decisions for these organ types are sometimes based on quality of life considerations, rather than survival alone. Commenters pointed out that medical and surgical therapy changes constantly, and it is difficult for transplant centers to set the upper and lower parameters in exhausting all available therapies before placing patients on the waiting list. Some commenters asked us to define ''all other appropriate medical and surgical therapies'' and questioned how compliance with this requirement would be determined.

Response: We understand the commenters' concerns that some transplant risk-benefit decisions are not based on survival alone and that it may be difficult for transplant centers to establish parameters for alternative medical and surgical therapies. Therefore, we are not finalizing our proposed requirement at § 482.90(a)(1).

Comment: Some commenters supported our proposal to require a psychosocial evaluation for prospective transplant candidates and suggested that a transplant center should designate qualified staff to perform the evaluation. One commenter suggested that prospective transplant candidates who have a history of psychiatric illness and substance abuse should be further evaluated by a psychologist or psychiatrist.

Response: We agree that a psychosocial evaluation should be performed by qualified staff. For good patient care, we expect that the individual who performs a psychosocial evaluation of a transplant candidate or prospective living donor will make a referral for further evaluation if a patient shows symptoms of, or has a history of, psychiatric illness or substance abuse. However, we have made no changes based on this comment.

Comment: Many commenters recommended changing our proposed language to state that a prospective transplant candidate or prospective living donor must receive a ''qualified social worker evaluation'' because the proposed language ''psychosocial evaluation'' is too ambiguous and does not indicate who conducts the evaluation. Other commenters recommended that a qualified social worker should be designated to perform the evaluation using the Standards for Social Work Services in ESRD Facilities developed by the ESRD Network of Texas, Inc. as the standardized assessment tool.

Response: We appreciate the commenters' recommendations. However, since there is more than one category of qualified professional who can conduct a psychosocial evaluation of a prospective transplant candidate, we have chosen to give transplant centers the flexibility to designate the type of qualified individual who will conduct the psychosocial evaluation. This individual may be a qualified social worker or another qualified individual.

In our view, there is no standardized psychosocial evaluation tool that would be applicable to all prospective organ transplant candidates. Therefore, this final rule, as proposed, provides a transplant center with the flexibility to select a standardized psychosocial evaluation tool or to devise its own psychosocial evaluation tool. We have made no changes based on this comment.

Comment: One commenter stated that it is impractical and inappropriate to require transplant centers to conduct a psychosocial evaluation of some prospective transplant candidates, such as infants and very small children, as well as patients who are acutely ill with fulminate hepatic failure or acute cardiomyopathy.

Response: In nearly all cases, a transplant center should ensure that patients receive a psychosocial evaluation prior to placement on the center's waiting list. However, we agree with the commenters that conducting a psychosocial evaluation is not always possible, for example, in emergency situations or when the patient is very young. Therefore, we have revised the regulation text at § 482.90(a)(1) to state that ''prior to placement on the center's waiting list, a prospective transplant candidate must receive a psychosocial evaluation, if possible.'' We expect transplant centers to perform psychosocial evaluations in every situation in which it is possible to do so.

Comment: A few commenters supported the requirement for determining and documenting a transplant candidate's blood type in medical records prior to being placed on the waiting list. However, one commenter suggested that we should refer to the UNet℠ system to determine a candidate's ABO blood type, instead

of establishing a new blood type documentation requirement.

Response: We are not establishing a new blood type documentation requirement. We require only that before a transplant center places a transplant candidate on its waiting list, the candidate's medical record must contain documentation of the candidate's blood type. Similarly, OPTN policies require a transplant program to be responsible for ensuring the accuracy of candidate ABO data on the waiting list. OPTN policies also include on-line verification of a candidate's ABO data against the source document by an individual other than the person initially entering the candidate's ABO data in UNet℠. The OPTN expects a transplant program to maintain records documenting that such separate verification of the source document against the entered ABO has taken place and make such documentation available for audit. Our requirements complement these OPTN policies. The individual who verifies the source document (which could be the determination of blood type in the candidate's medical record against the UNet℠) may simply annotate the verification in the medical record.

Comment: A commenter questioned the rationale for requiring documentation of the patient selection criteria used. One commenter stated that documenting patient selection criteria would be time-consuming and a departure from current practice. Another commenter suggested that adherence to some written basic patient selection criteria or cross-referencing the patient selection criteria should be adequate evidence of compliance. A few commenters stated that the documentation of patient selection criteria, including the evaluation process and analysis of extensive medical work-up, would add administrative burden to transplant centers and increase Medicare expenses.

Response: The rationale for requiring documentation of the patient selection criteria used is to ensure that the transplant center's written patient selection policies and procedures are consistently implemented and that this is reflected in medical records. We agree that repeating a written narrative of all previous pre-transplant evaluation processes and medical work-ups would be burdensome. However, in documenting the patient selection criteria used, a transplant center may choose to use electronic formats, forms, or checklists to indicate the applicable criteria, as set forth in the center's own policies and procedures manual. We believe that any administrative burden associated with the patient selection criteria documents will be minimal and will not raise Medicare expenses appreciably.

Comment: A few commenters supported the requirement that living donor selection criteria must be consistent with general medical ethics. Commenters stated that selection criteria are important in bringing some standardization to the living donor evaluation and selection processes. A commenter recommended giving flexibility to transplant centers to evaluate medical ethics issues on a case-by-case basis. However, one commenter stated that there is no consensus on what constitutes medical ethics. Another commenter requested more explicit clarification of the meaning of general medical ethics.

Response: We expect a transplant center to assess the prospective living donor carefully to ensure, insofar as possible, that donation will not cause long-term harm to the individual's health. Furthermore, we expect transplant centers to apply the ethical principle of ''equipoise'' to assess whether the benefits to both the donor and the recipient outweigh the risks associated with the donation and the transplantation. We believe the provisions set forth in this final rule provide flexibility for transplant centers to evaluate every prospective living donor individually, using the same medical ethics they would use in providing health care to any patient. No changes were made based on these comments.

Comment: A commenter questioned if Internet donor matching is ethical.

Response: The commenter is correct that the transplant community has not reached consensus on the ethics of certain donation practices, such as Internet donor matching. However, such issues are beyond the scope of this final rule.

Comment: Some commenters suggested adopting the OPTN Ad Hoc Living Donor Committee Living Liver and Kidney Donor Evaluation Guidelines or the Living Donor Evaluation Criteria developed by the American Society of Transplantation.

Response: We support the concept of incorporating professional guidelines into a transplant center's living donor selection policies. However, we believe incorporating the suggested guidelines or evaluation criteria into this final rule would be too prescriptive and would not provide centers with sufficient flexibility. We made no changes based on this comment.

Comment: Although some commenters supported medical and psychosocial evaluation of living donors, one commenter did not support the requirement for a living donor to receive a psychosocial evaluation, as it might delay transplantation and would add to the cost of the transplantation. The commenter noted that, in the case of parent to child donation, the psychosocial evaluation would not be warranted.

Response: Transplant centers are free to include a process in their policies and procedures to respond to emergency situations when it may not be possible to conduct a psychosocial evaluation prior to donation. However, in the absence of such a situation, we expect transplant centers to conduct psychosocial evaluations of all prospective living donors. An evaluation can assist the prospective living donor in evaluating the pros and cons of donating and the potential psychological impact of donating and thus aid the individual in making an appropriate donation decision. Even a parent donating to a child may feel conflicted; for example, a parent may worry about the possible impact of the parent's donation on other children in the family.

Comment: One commenter supported the documentation of living donor suitability in medical records. However, some commenters had concerns that such documentation in the transplant candidate's medical records would compromise the privacy of the donor's individually identifiable health information and violate the HIPAA regulations, putting transplant centers at legal risk. Another commenter stated that this requirement deprives the potential living donor of an exit out of the donation process if the individual is reluctant to donate but prefers the transplant candidate to think he or she cannot donate for medical reasons.

Response: We believe the commenters have valid concerns, and we agree that documentation of a living donor's suitability for donation in the transplant recipient's medical records would be inappropriate. Therefore, we have eliminated the proposed requirement at § 482.90(b)(2) to document the transplant recipient's medical record with the living donor's suitability for donation. However, we have finalized our proposal to require documentation of the living donor's suitability for donation in the living donor's medical record. (See § 482.90(b)(2).)

Availability of Patient Selection Criteria

In the proposed rule, we requested comments on whether transplant centers should be required to make the

patient selection criteria available to patients routinely or upon request.

Comment: One commenter stated that providing transplant patients with patient selection criteria would restore public trust in the transplant system and ensure fairness in organ allocation. However, another commenter stated that providing candidates with patient selection criteria may set unrealistic expectations in the complex organ allocation and transplantation process. A few commenters recommended that a copy of the patient selection criteria should be given to patients only if requested.

Response: We agree that the knowledge of a transplant center's patient selection criteria would help a patient to better understand his or her treatment options. However, given that transplantation is not a straightforward decision, we agree with the commenter who expressed concern that providing the patient selection criteria to patients may lead to misunderstanding or give some patients unrealistic expectations of their likelihood of receiving a transplant. Some patients may want to rely on their surgeons and physicians to give them advice and recommendations about transplantation. Therefore, this final rule requires a transplant center to provide a copy of its patient selection criteria to a patient only upon the patient's request.

We are sympathetic to the view of the commenter who said that providing copies of patient selection criteria to patients would ensure fairness in organ allocation. We believe that additional transparency in the selection process can further the goal of equity in transplantation and give dialysis facilities a tool to ensure that referral of dialysis patients to kidney transplant centers for evaluation is fair and non-discriminatory. That is, once a dialysis facility knows the specific patient selection criteria used by each kidney transplant center in its vicinity, it can better ensure that it refers all patients who may be eligible for transplantation. Therefore, we have added a requirement to this final rule specifying that a kidney transplant center must provide a copy of its transplant patient selection criteria to a transplant candidate or a dialysis facility, at the request of the patient or the facility. (See § 482.90(a)(4).)

We note that a patient who believes that a transplant center's patient selection criteria are unfair or discriminatory or that a transplant center has not followed its patient selection criteria may find a remedy in the grievance process of the hospital in which the transplant center is located. Section 482.13, Patient Rights, requires hospitals to protect and promote each patient's rights. Section 482.13(a)(2) further requires that hospitals establish a grievance process for the prompt resolution of patient grievances and that the hospital's grievance procedures are clearly explained to the patient.

Condition of Participation: Organ Recovery and Receipt (Proposed § 482.92)

We proposed that transplant centers must have written protocols to validate donor-recipient matches and other vital data for deceased organ recovery, organ receipt, and living donor transplantation. We proposed assigning responsibility to the transplanting surgeon for ensuring the medical suitability of donor organs for transplantation into the intended recipient.

We proposed that a transplant center's organ recovery team would have to review and compare the recipient and donor data with the recipient blood type and other vital data before recovery took place. We also proposed requiring that, when an organ arrives at a transplant center, the transplanting surgeon and at least one other individual at the transplant center must verify prior to transplantation that the donor's blood type and other vital data indicate that the donor's organ is compatible with transplantation of the intended recipient.

We proposed that if a center performed living donor transplants, the transplanting surgeon and at least one other individual at the transplant center would be required to verify that the living donor's blood type and other vital data indicated that the donor's organ is compatible for transplantation of the intended recipient, immediately before the removal of the living donor organ(s) and, if applicable, prior to the removal of the recipient's organ(s).

Following are summaries of the comments we received and our responses.

Comment: Some commenters supported the proposed requirement for transplant centers to have written protocols to validate donor-recipient compatibility in organ recovery, receipt, and transplantation to prevent unintended transplantation of organs mismatched by blood type. However, a commenter stated that protocols for validation of data may pose a legal risk for transplant centers.

Response: A crosscheck verification of the donor's blood type with the blood type of the intended recipient is a critical step in organ allocation and transplantation. Therefore, in this final rule, as we proposed, we require transplant centers to have written protocols to ensure that this essential process takes place. We believe that consistent application of such sound protocols ultimately will reduce legal risks for transplant centers.

Comment: A commenter stated that it is impossible to be inclusive of all possible scenarios encountered in organ recovery; therefore, the use of a written protocol for organ recovery would be limited.

Response: We recognize that the unexpected may happen during organ recovery. However, a well-written organ recovery protocol should anticipate as many of these scenarios as possible.

Comment: Some commenters disagreed that the transplant surgeon should be fully responsible for suitability of donor organs during organ recovery because:

(1) Information provided by an OPO may not be accurate;

(2) At the time of organ recovery, the identity of the intended recipient may not be known; and

(3) At the time of organ recovery, information about the organ donor may not be complete.

Response: The requirement does not mean that the transplant surgeon is responsible for the suitability of donor organs prior to or during recovery. The transplant surgeon is responsible for ensuring the medical suitability of a donor organ for transplantation into the intended recipient only after the organ has arrived at the transplant center. If the transplant surgeon makes the determination of medical suitability based on inaccurate information provided by the OPO about the donor organ (for example, the paperwork that accompanies the organ to the transplant center is marked with the wrong blood type), the transplant surgeon will not be held responsible for his or her determination of medical suitability.

Comment: A commenter suggested that the transplant coordinator should be responsible for blood type verification.

Response: Transplant centers may delegate this responsibility to transplant staff or the transplant coordinator. No change was made based on this comment.

Comment: Some commenters stated that the proposed blood type validation is duplicative of OPTN policies; therefore, additional requirements would not be necessary. Some commenters suggested that the OPTN policies and Medicare requirements should be consistent.

Response: The commenters are correct that our requirement is similar to the OPTN policy, which requires a

transplant center, upon receipt of an organ and prior to transplantation, to perform and document crosscheck verification of the donor's blood type with the blood type of the intended recipient. As we have stated previously in this preamble, with the exception of OPTN data submission requirements, OPTN policies are not enforceable unless they are approved by the Secretary under 42 CFR 121.4.

Comment: Some commenters suggested that our proposals for organ recovery were unnecessary. For example, a commenter stated that organ procurement procedures start before the recipient is identified or the transplant center is notified. Another commenter stated that many large OPOs already have developed protocols for organ recovery teams that recover organs for the OPO or for transplant centers, which means that transplant centers would have minimal involvement in the organ recovery process. However, another commenter agreed with our proposal and said that a transplant center's recovery team should validate donor and recipient blood type and other vital data before organ recovery takes place.

Response: We recognize that in many cases, transplant centers may have little involvement in the process of organ recovery. Therefore, we have revised the regulation text at § 482.92(a) to reflect that when the intended recipient is known, and the transplant center sends a team to recover organ(s), the transplant center's recovery team must review and compare the donor data with the recipient blood type and other vital data before organ recovery takes place.

Comment: A commenter suggested that instead of requiring at least one other individual to verify donor-recipient blood type and vital information, we should specify that the individual must be a licensed health care professional.

Response: We agree with the commenter. We have changed the regulatory text at § 482.92(b) to require that after an organ arrives at a transplant center, prior to transplantation, the transplanting surgeon and another licensed health care professional must verify that the donor's blood type and other vital data are compatible with transplantation of the intended recipient. In addition, we have changed the regulatory text at § 482.92(c) to say that if a center performs living donor transplants, the transplanting surgeon and another licensed health care professional at the center must verify that the living donor's blood type and other vital data are compatible with transplantation of the intended recipient immediately before the removal of the donor organ(s) and, if applicable, prior to the removal of the recipient's organ(s). Since cross checking donor and recipient information generally is performed in the operating room just prior to transplantation, nurses and other licensed health care professionals should be readily available.

Condition of Participation: Patient and Living Donor Management (Proposed § 482.94)

We proposed that transplant centers must have written patient management policies for the pre-transplant, transplant, and discharge phases of transplantation. We proposed that if a center performs living donor transplants, it must have written donor management policies for the donor evaluation, donation, and discharge phases of the living organ donation. We proposed that a transplant center must ensure that each transplant patient and living donor is under the care of a multidisciplinary patient care team coordinated by a physician throughout all phases of the transplantation or living donation.

We proposed that transplant centers must keep their waiting lists current, including updating waiting list patients' clinical information on an ongoing basis. We also proposed that a transplant center must remove a patient from its waiting list if the patient receives a transplant, if the patient dies, or if there is any other reason that the patient should no longer be on a center's waiting list.

We proposed requiring transplant centers to notify the OPTN of a patient's removal from the center's waiting list no later than 24 hours after the removal.

We proposed that transplant centers must maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a center's waiting list and who is admitted for organ transplantation. For each patient who receives an evaluation for placement on a center's waiting list, we proposed that the center must document in the patient's record that the patient is informed of his or her transplant status, including notification of: (1) The patient's placement on the center's waiting list; (2) the center's decision not to place the patient on its waiting list; or (3) the center's inability to make a determination regarding the patient's placement on its waiting list because further clinical testing or documentation is needed.

We proposed that once a patient is placed on a center's waiting list, the center must document in the patient's record that the patient has been notified of: (1) His or her placement status (at least once a year, even if there was no change in the patient's placement status); and (2) his or her removal from the waiting list for reasons other than transplantation or death no later than 10 days after removal.

We proposed that kidney transplant centers must document in the patient's record that both the patient and the patient's usual dialysis facility have been notified of the patient's transplant status and of any changes in the patient's transplant status.

We proposed that when a patient is admitted for transplantation, the patient's record must contain written documentation of multidisciplinary patient care planning during the pre-transplant period and multidisciplinary discharge planning for the patient's post-transplant care.

We proposed that transplant centers must make social services, furnished by qualified social workers available to transplant patients, living donors, and their families. We proposed that a qualified social worker is an individual who meets licensing requirements in the State in which he or she is practicing and: (1) Has completed a course of study with specialization in clinical practice and holds a master's degree from a graduate school of social work accredited by the Council on Social Work Education; or (2) has served for at least 2 years as a social worker, 1 year of which was in a transplantation program, and has established a consultative relationship with a social worker.

We proposed that transplant centers must make nutritional assessment and diet counseling services furnished by a qualified dietitian available to all transplant patients and living donors.

We proposed that a qualified dietitian is an individual who: (1) Is eligible for registration by the American Dietetic Association under its requirements in effect on June 3, 1976 and has at least 1 year of experience in clinical nutrition; or (2) has a baccalaureate or advanced degree with major studies in food and nutrition or dietetics and has at least 1 year of experience in clinical nutrition.

We also are responding to comments we received on the ESRD proposed rule from dialysis facilities relating to transplant referral tracking of dialysis patients and the grandfather requirement for social workers. Although these comments were submitted along with comments on the ESRD proposed rule (February 4, 2005, 70 FR 6184), we are responding to them in the preamble to this final rule because they are relevant to our

proposed requirements for notification of waiting list patients and our proposed requirements for social workers.

Following are summaries of the comments we received and our responses to the comments.

Comment: Commenters agreed that transplant centers should play an active role in the care and management of transplant patients. Some commenters suggested that transplant centers should be required to provide pre-transplant and post-transplant care to transplant recipients in conjunction with the recipient's local provider team. However, many commenters stated that transplant centers should not be held accountable for transplant patients' pre- and post-transplant care because many waiting list patients do not live near the transplant center and are cared for by their local providers, particularly in the case of dialysis patients. Kidney transplant patients usually receive their pre- and post-transplant care from their local nephrologists and dialysis facilities. Commenters stated that pre-transplant care planning for kidney patients is the responsibility of the dialysis facilities where the patients receive care.

Response: As stated previously, we agree with the commenters that the care of transplant patients is best coordinated by local health care providers and transplant centers. Transplant patients require clinical evaluation before being placed on the waiting list, clinical care while they are on the waiting list, and follow-up monitoring after transplantation. In most cases, while transplant candidates are waiting for suitable organs, they continue to receive non-transplant-related routine medical care from their local health care providers and (for kidney patients) dialysis facilities, rather than from the transplant center where they are listed. Therefore, based on public comments, we have not finalized our proposed requirement at § 482.94 that transplant centers must have written patient management policies for the pre-transplant phase of transplantation or our proposed requirement that they must provide pre-transplant care to transplant patients.

We agree with the commenters that transplant patient management is better coordinated with the transplant patient's local providers, and we expect that for the most part, this is already a standard practice. However, we see no reason to prescribe explicitly how transplant centers should work with other providers, with the exception of dialysis facilities.

The relationship between dialysis facilities and kidney transplant centers is unique because dialysis facilities treat and monitor their patients more frequently than other health care providers. Any changes in a dialysis patient's' clinical status may affect his or her transplant suitability. Thus, it is important for kidney transplant centers to have open and frequent communication with dialysis facilities to ensure that all transplant-related issues are communicated clearly to the patient and to the patient's provider(s) of care. Based on these comments, we have added a requirement at § 482.104(a) that a kidney transplant center must have written policies and procedures for ongoing communication with dialysis patients' local dialysis facilities.

Coordination also ensures that the transplant center has the information about the patient's status that it needs to keep its waiting list and the OPTN's waiting list current. For example, a patient may have to be removed from the waiting list because he or she has become too ill to receive a transplant. Therefore, we are finalizing the proposed requirement at § 482.94(c) as follows. Section 482.94(c)(1) specifies that for each patient who receives an evaluation for placement on a center's waiting list, the center must document in the patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) has been informed of his or her transplant status, including notification of: (i) The patient's placement on the center's waiting list; (ii) The center's decision not to place the patient on its waiting list; or (iii) The center's inability to make a determination regarding the patient's placement on its waiting list because further clinical testing or documentation is needed. Section 482.94(c)(2) requires that if a patient on the waiting list is removed from the waiting list for any reason other than death or transplantation, the transplant center must document in the patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) was notified no later than 10 days after the date the patient was removed from the waiting list

For post-transplant care, we expect a transplant center to use the discharge planning process to coordinate transplant-related follow-up care. (See § 482.94(c)(3)(ii).) As a general rule, patients receive several months of post-transplant care from the transplant center that performed the transplant, even if they do not live near the transplant center. After that, patients often continue to receive care from the transplant center for an extended period of time in conjunction with their local physician or dialysis center. Coordination of care ensures that the transplant center will have access to the patient follow-up data it needs to abide by the OPTN data collection and submission policies.

Comment: One commenter stated that the provision for multidisciplinary patient care planning is overly detailed and would place a burden on centers.

Response: We disagree with the commenters. We believe the multidisciplinary patient care planning provision proposed at § 482.94(c)(4) is flexible and general in nature. We believe the requirements will allow a transplant center to assemble a multidisciplinary patient care team using in-house hospital staff, which should create little or no extra burden. Therefore, we are finalizing this requirement as proposed.

Comment: One commenter stated that the proposed patient care requirements are duplicative of the JCAHO survey standards for inpatient care planning and discharge planning. Another commenter noted that the OPTN policies already address transplant care and patient management guidelines.

Response: We agree that there are similarities between the JCAHO survey standards for inpatient care planning and discharge planning and our requirements for patient care in this final rule. However, some requirements in this final rule (such as living donor care, management of the waiting list, and patient records) are absent from JCAHO's survey standards for acute care hospitals. Furthermore, even if Medicare requirements were identical to JCAHO standards and OPTN policies, this fact would not eliminate the need to incorporate the requirements into our regulations because JCAHO standards and the OPTN's policies are not legally enforceable by CMS.

Comment: Many commenters stated that kidney transplant centers should be exempt from the requirement for a written long-term care plan because kidney transplant candidates are usually cared for by their referring physicians, nephrologists, social workers, dietitians, and dialysis facilities while awaiting transplants. Some commenters suggested that instead of developing a care plan, kidney transplant centers should be required only to obtain a copy of the patient's long-term care plan from the dialysis facility and keep it with the transplant candidate's medical records.

Response: The commenters may have misunderstood the proposed patient management requirement. We are not requiring transplant centers to develop long-term care plans for transplant patients. We agree that this is the

responsibility of each patient's local health care providers and dialysis facility, as appropriate. As stated earlier, we strongly encourage transplant centers to collaborate with local providers and dialysis facilities to tailor patient management policies to their patients' needs. Given that it is a standard practice for health care providers to request medical records from other providers who are actively treating their patients, we do not believe we need to require a transplant center to obtain a copy of the patient's long-term care plan from the dialysis facility, nor do we need to exempt kidney transplant centers from these requirements. No changes have been made to this final rule based on these comments.

Comment: One commenter supported the proposal that living donors should be under the care of a multidisciplinary team to safeguard their interests and well-being. The commenter suggested that we should require centers to be responsible for living donors' post-discharge issues or complications and provide specialists to follow living donors.

Response: Since some living donors may receive immediate post-donation care in hospital units outside the transplant center, we want to ensure that living donor care is well coordinated.

We expect transplant centers to coordinate follow-up care for living donors upon discharge as well. Although this final rule does not specifically delineate transplant centers' responsibilities for living donors' post-discharge care, we expect a transplant center to provide care, as needed, if a living donor experiences donation-related problems or complications post-discharge.

Comment: Many commenters commended us for our clarity in describing the waiting list management requirements that would positively impact the organ allocation system. The commenters stated that it is important for transplant centers to update the status of waiting list patients continuously to increase the efficiency of organ allocation and ultimately reduce organ wastage and organ discard rates. However, a few commenters stated that the waiting list management requirements are overly detailed and may put centers at legal risk.

Response: We disagree that the waiting list management standard is overly detailed. The waiting list management requirements in this final rule are steps transplant centers must take to help the OPTN keep the waiting list current, so that: (1) Organ allocation is prioritized based on medical urgency and other relevant factors; (2) OPOs do not waste valuable time contacting centers about patients who should no longer be on the waiting list; and (3) organ wastage is minimized.

We have no evidence that keeping its waiting list current will create a legal risk for a transplant center.

Comment: One commenter suggested that we should specify how frequently transplant centers must update their waiting lists (that is, daily, weekly, or monthly).

Response: We are not imposing an arbitrary timeframe for transplant centers to keep their waiting lists up to date. The availability of waiting list patients' clinical information varies from patient to patient, and clinical information may change frequently or infrequently. We expect transplant centers to update their waiting lists, including updates of clinical information and removal of patients from waiting lists an ongoing basis as the information becomes available. For clarity we have added ''on an ongoing basis'' at § 482.94(b) to emphasize that transplant centers must keep their waiting lists up to date.

Comment: Some commenters expressed appreciation that we did not propose to mandate an annual evaluation of all patients on the waiting list. One commenter suggested that waiting list management should be clinically driven. That is, we should require centers to identify ''high risk'' transplant candidates and evaluate them annually. A commenter suggested requiring centers to conduct periodic clinical re-evaluations of transplant candidates to enhance updating of clinical information in those patients' medical records and their information on the waiting list.

Response: We developed the requirement for transplant centers to update clinical information for their waiting list patients on an ongoing basis based on the assumption that updating of patients' clinical information is clinically driven. We understand that some patients are in critical condition, requiring more intense evaluation and monitoring, and other patients remain stable for longer periods of time. We expect transplant centers to keep their waiting lists updated accordingly. We expect that transplant centers will determine how often waiting list patients should be evaluated, based on the acuity of the individual patient. No changes were made in this final rule based on these comments.

Comment: A commenter stated that it is unreasonable to expect large centers with long waiting lists to update all patients' clinical information on an ongoing basis because the requirement would be too burdensome.

Response: We believe it is essential for a transplant center to stay abreast of its waiting list patients' clinical status and keep its waiting list updated on an ongoing basis so that when an organ offer is made, the transplant center knows the clinical status of the potential recipient. If a long waiting list is the reason for a center's failure to update waiting list patients' clinical status, the transplant center may need to re-evaluate its policies to determine if the number of patients on its waiting list is beyond its capacity to manage.

Comment: Some commenters stated that managing a transplant center's waiting list is a very complex task and is already subject to OPTN oversight. Some commenters suggested that the OPTN should be the entity to set guidelines for waiting list management, and one commenter recommended that we should ask the OPTN to develop guidelines for transplant centers. Another commenter suggested that the OPTN should incorporate and publish the transplant waiting list management guidelines developed by the American Society of Transplant Surgeons (ASTS). Commenters said that our regulations should require only that transplant centers comply with OPTN waiting list policies.

Response: As appropriate, we have included OPTN patient waiting list policies in this final rule for oversight and enforcement purposes. The OPTN has waiting list management policies that go beyond our requirements, including patient screening and listing criteria, waiting time modifications, multiple listings, and removal of transplant candidates from waiting lists. As we proposed at § 482.94(c), we have included some OPTN patient waiting list policies in this final rule for oversight and enforcement purposes. Suggestions regarding the OPTN's incorporation of specific guidelines, such as those developed by ASTS, fall outside the purview of this final rule and should be addressed to the OPTN.

Comment: Some commenters stated that dialysis facilities do not always inform kidney transplant centers about changes in the clinical status of their dialysis patients. The commenters suggested that transplant centers, referring nephrologists, and dialysis facilities all should be held accountable for collaboration and communication regarding the clinical and listing status of patients on the waiting list. The commenter said that the collaboration process would help the transplant

center to keep patients' clinical information current.

Response: We agree. Based on public comments, we have added a requirement for kidney transplant centers to have written policies and procedures for ongoing communication with dialysis patients' local dialysis facilities. (See § 482.104(a).) We believe this requirement will resolve the commenters' concern about insufficient communication or lack of communication between transplant centers and dialysis facilities.

Comment: A commenter stated that the requirement to notify the United Network of Organ Sharing (UNOS) (i.e., the OPTN Contractor) within 24 hours after a patient's removal from the center's waiting list does not take into consideration the inaccessibility of the UNet℠ over the weekend for on-call staff.

Response: UNet℠ is available 24 hours a day, 7 days a week to the transplant community. Transplant centers need to provide access for on-call or weekend staff so that they can notify the OPTN timely outside of normal business hours.

Comment: A commenter stated that timely notification to the OPTN about patients' removal from the waiting list is affected by data provided by dialysis facilities and local clinicians. One commenter suggested that we purchase software to help centers interface with dialysis facilities timely.

Response: As we developed the proposed ESRD rule, we recognized the need for dialysis facilities to inform transplant centers about changes in the status of kidney transplant candidates.

Although currently there is no software available to provide an interface between transplant centers and dialysis facilities, we do not expect transplant centers to have difficulty communicating with dialysis facilities.

Comment: Some commenters supported the requirement for centers to notify each patient who is evaluated for transplant of his or her transplant status. However, some commenters stated that our patient notification requirements would be duplicative of OPTN policies.

Response: Current OPTN bylaws for transplant hospitals include notification of patients in writing within 10 business days of: (1) A patient's placement on the waiting list, including the date the patient was listed; (2) completion of a patient's evaluation as a candidate for transplantation, if the evaluation has been completed and the patient will not be placed on the waiting list; or (3) removal from the waiting list as a transplant candidate for reasons other than transplantation or death. Further, transplant hospitals are expected to maintain documentation of these notifications and make the documentation available to the OPTN. As we proposed at § 482.94(c)(2), we have incorporated similar notification policies into this final rule for purposes of oversight and enforcement. In addition, as proposed at § 482.94(c)(3), this final rule requires a transplant center to document that it has notified the patient and dialysis facility, if applicable, if the transplant center is unable to make a decision whether to place the patient on the waiting list because further clinical testing or documentation is needed, as required by § 482.94(c)(1)(iii).

Comment: A commenter stated that communicating waiting list status to patients via mail is too labor-intensive. A few commenters stated that our impact analysis in the proposed rule underestimated the cost of notifying patients and dialysis facilities. One commenter stated that the cost quoted to notify patients and dialysis facilities does not include management oversight time and expenses. Another commenter suggested that centers should use a letter to notify patients whether they will be placed on the waiting list and use phone calls for other types of communication.

Response: As we proposed, the patient notification requirements in this final rule do not mandate how transplant centers will notify patients and dialysis facilities about patients' waiting list status. Transplant centers have the flexibility to determine how they will communicate such information to patients and dialysis facilities. Further discussion of the paperwork and the economic impact of these requirements are found in the Collection of Information and Impact Analysis sections of this preamble.

Comment: Some commenters stated that the yearly requirement to notify transplant patients goes beyond the OPTN requirement and is unreasonable, costly, prescriptive, burdensome, and impractical.

Response: We have carefully evaluated all the public comments we received on this issue and concluded that annual notification to patients would be unduly burdensome for transplant centers and is not necessary, as long as transplant centers can document that they notified transplant candidates, as appropriate, about the transplant candidate's placement status in accordance with § 482.94(c) in this final rule. Therefore, we are not adopting the yearly notification requirement we proposed at § 482.94(c)(2)(i).

However, as we proposed at § 482.94(c), we are requiring that if a transplant center evaluates a patient for placement on the waiting list, the center must document in the patient's record that the patient is informed of his or her transplant status, including notification of: (1) The patient's placement on the center's waiting list; or (2) the center's decision not to place the patient on its waiting list. Furthermore, as we proposed, once a patient is placed on a center's waiting list, the center must document in the patient's record that the patient is notified of his or her removal from the waiting list for reasons other than transplantation or death no later than 10 days after the patient's removal from the center's waiting list.

To clarify that the requirement for notifying patients of their status after they have been evaluated for transplantation is the same for all patients but that a kidney patient's usual dialysis facility also must be notified, we have removed proposed section 482.94(c)(3) and added language to sections 482.94(c)(1) and (2). Section 482.94(c)(1) now reads in part, ''For each patient who receives an evaluation for placement on a center's waiting list, the center must document in the patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) has been informed of his or her transplant status, including notification of * * *.'' Section 482.94(c)(2) now reads in part, '' If a patient on the waiting list is removed from the waiting list for any reason other than death or transplantation, the transplant center must document in the patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) was notified * * *.''

Comment: A commenter stated that patients should take some responsibility for waiting list accuracy. Another commenter suggested that transplant patients should be given the ''Patient Bill of Rights and Responsibilities'' package in which the patient acknowledges in writing that he or she has the responsibility to keep the transplant center informed of his/her whereabouts.

Response: We agree that waiting list patients should keep the center or centers where they are listed informed of their whereabouts and informed of any other relevant information. We encourage transplant centers to educate potential transplant candidates about their responsibilities. However, we have made no changes based on this comment.

Comment: A commenter suggested that a center should be found in

compliance if it documents that it made a reasonable attempt to notify a patient without actually succeeding.

Response: When notification of a waiting list patient or a prospective waiting list patient is required under this final rule, we expect the transplant center to make a concerted effort to locate and notify the patient. Nevertheless, we understand there may be circumstances in which the patient cannot be found. At a minimum, a transplant center should maintain documentation in the medical record that it made several attempts to contact the patient.

Comment: Some individuals who commented on the ESRD proposed rule stated that dialysis facilities should relinquish transplantation referral tracking responsibility once the referral has been made. Commenters expressed concerns that some transplant centers do not communicate with dialysis facilities regularly. One commenter stated that transplant centers should provide dialysis facilities with the information they need to monitor transplantation status.

Response: As we proposed, and as adopted in this final rule, a kidney transplant center bears considerable responsibility for patient tracking once a dialysis facility has referred a patient for evaluation. Section 482.94(c)(1) requires documentation of notification of the patient of his or her placement on the center's waiting list, the center's decision not to place the patient on its waiting list, or the center's inability to make a determination regarding the patient's placement on its waiting list because further clinical testing or documentation is needed. Under § 482.94(c)(3), transplant centers must document in the patient's medical record that both the patient and the patient's local dialysis facility have been notified of the patient's transplant status and of any changes in the patient's transplant status (in accordance with § 482.94(c)(1)).

Comment: Many commenters supported the requirement that transplant centers must make social services furnished by qualified social workers available to transplant patients, living donors, and their families. Some commenters recommended that transplant centers should be required to provide transplant patients and living donors with ongoing access to qualified transplant social workers for continuity of care after discharge. One commenter inquired about the time frame for post-transplant social services provided by transplant centers and the potential for Medicare reimbursement for the services.

Response: Under the final rule and as we proposed, transplant centers are responsible for making social services furnished by a qualified social worker available to all transplant patients, living donors, and their families while a transplant patient or living donor is hospitalized. For Medicare beneficiaries (and their living donors), the services are often reimbursed. We did not propose requiring, nor does this final rule require, transplant centers to provide post-discharge social services to all transplant recipients or living donors. Nonetheless, we expect any social services needed post-discharge would be arranged through the discharge planning process. Some centers may choose to continue to provide such services to patients and living donors even though they may not be Medicare reimbursable. Medicare reimbursement for post-transplant social services outside the hospital setting falls outside the purview of this rule.

Comment: Many commenters supported the proposed definition of a qualified social worker as an individual with a master's degree in social work (MSW). Commenters noted that the MSW degree requires an additional 900 hours of specialized training beyond a baccalaureate degree in social work, which prepares the individual with an MSW to work independently in the transplant setting where supervision and peer support is not always readily available.

Many commenters recommended that we not allow social work experience to substitute for an MSW, as we proposed. We proposed permitting social workers to qualify if they served for at least 2 years as a social worker, 1 year of which was in a transplantation program, and had established a consultative relationship with a social worker who qualified under our requirements for social workers with a master's degree. (See proposed § 482.94(d)(2).) Conversely, in the ESRD proposed rule (70 FR 6184), we proposed eliminating a provision found in the current ESRD regulations at § 405.2102 (which applies both to dialysis facilities and to kidney transplant centers), which defines a social worker, in part, as an individual who, ''* * * Has served for at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976 * * *''

Many who commented on the ESRD proposed rule said that we should retain this ''grandfather clause'' for non-MSWs so that currently employed non-MSWs working as social workers do not lose their jobs. Some commenters said that experienced non-MSW social workers are competent and have a lot to offer, and they recommended that we continue the grandfather clause.

Response: In general, we agree with commenters who stated that a social worker with an MSW degree is the best qualified individual to evaluate and assess transplant candidates, recipients, families, and living donors who are facing multiple psychosocial stressors. However, we also agree with commenters who said that non-MSW social workers who were employed as such prior to September 1, 1976 have much to offer patients and families. We also believe that there should be one standard for all transplant centers.

To reconcile the conflicting viewpoints of commenters opposed to non-MSW social workers providing social services in transplant centers and commenters who urged us to retain the grandfather clause in the ESRD final rule, we have finalized the requirements for an individual to be a qualified social worker in any transplant center (not just a kidney transplant center) as follows. This final rule states that a qualified social worker is an individual who meets licensing requirements in the State in which he or she practices and: (1) Has completed a course of study with specialization in clinical practice and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education; or (2) is working as a social worker in a transplant center as of the effective date of this final rule and has served for at least 2 years as a social worker, 1 year of which was in a transplantation program, and has established a consultative relationship with a social worker who is qualified under § 482.94(d)(1).

This grandfather clause applies only to individuals who are currently employed as social workers in a transplant center as of the effective date of this final rule. Although we believe the number of these individuals to be small, we do not intend that these employees should lose their jobs because of the deletion of the ''grandfather clause.''

Comment: A commenter suggested that we adopt the OPTN policies for the psychosocial services that transplant centers should offer without defining the required qualifications for a social worker.

Response: We do not agree that adopting OPTN policies without establishing requirements for social worker qualifications would serve the best interests of patients and living donors. As commenters overwhelmingly agreed, master's degree-prepared social workers are best qualified to provide

social services to transplant candidates and recipients, as well as living donors. Social workers often perform psychosocial evaluations of prospective transplant candidates and prospective living donors, and social workers provide critical services to transplant recipients and living donors during the inpatient and discharge phases of donation and transplantation. For example, prior to discharge, social workers provide counseling services to transplant recipients to assist them in maintaining the resolve they need to remain compliant with their immunosuppressive and other medications, which are necessary to prevent graft failure. We made no changes based on this comment.

Comment: A commenter recommended that a qualified social worker should have training in, and knowledge of, pediatric transplant issues.

Response: We agree that qualified social workers should have transplant training and knowledge of pediatric transplant issues, which can be achieved through on-the-job training or continuing education, if they are providing services in a pediatric center. We expect transplant centers to ensure that qualified social workers working in pediatric transplant programs receive ongoing staff development training to better handle issues that are unique to pediatric transplantation. We made no changes based on this comment.

Comment: Some commenters supported the requirement for transplant centers to have nutritional assessments and diet counseling services furnished by a qualified dietitian available to all transplant patients and living donors. One commenter stated that medical nutrition therapy is important for patients and living donors. However, some commenters stated that transplant centers should not be responsible for transplant candidates' pre-transplant nutritional care or care during the evaluation phase for transplant, which is usually provided by candidates' local providers. A few commenters stated that transplant centers should not be required to provide ongoing post-transplant nutritional services to patients and living donors. The commenters requested clarification of the time frame for nutritional services provided to post-transplant patients, and stated that Medicare should reimburse for such services.

Response: We agree that pre- and post-transplant nutritional care is usually provided by transplant patients' and living donors' local health care providers. This final rule requires transplant centers to provide nutrition services to transplant recipients and living donors only during their inpatient stay. For example, a transplant recipient may need to be counseled on the modification of his or her dietary regimen after organ transplant or a living donor may need to be counseled for his or her temporary adjustment in nutritional intake after living organ donation. These services are part of the hospital inpatient services reimbursed by Medicare for beneficiaries and often for their living donors.

Comment: Some commenters suggested that living donors, particularly living kidney donors, should be exempt from nutritional services since they are healthy individuals.

Response: Although living donors are usually healthy individuals, we believe they should receive the same care provided to transplant recipients. Under the final rule and as proposed, transplant centers are responsible for making nutritional assessment and dietary counseling services furnished by a qualified dietitian available to all living donors while they are hospitalized for organ donation.

Comment: A commenter suggested that we should adopt the OPTN policy for nutritional services without defining the qualifications for a qualified dietitian.

Response: Currently, the OPTN does not have a policy for nutritional services furnished by transplant centers.

Comment: One commenter suggested adopting the Medical Nutrition Therapy (MNT) regulation definition of ''qualified dietitian.'' A few commenters suggested that the definition of a qualified dietitian in the transplant center rule and the ESRD rule should be consistent.

Response: We have not used the MNT definition for registered dietitian in this final rule because it includes both registered dietitians and other nutritional professionals, and we believe this may cause confusion. However, we have revised the proposed requirements at § 482.94(e).

In this final rule, we require that a qualified dietitian must be a registered dietitian with the Commission on Dietetic Registration (CDR), who meets the practice requirements in the State in which he or she is employed. (See § 482.94(e).) For the most part, these requirements are similar to those included in the proposed rule for new conditions for coverage for ESRD facilities published February 4, 2005 (70 FR 6184). To date, the ESRD facility final rule has not yet been published.

Condition of Participation: Quality Assessment and Performance Improvement (QAPI) (Proposed § 482.96)

We proposed that every transplant center must develop, implement, and maintain a written, comprehensive, data-driven QAPI program designed to monitor and evaluate the performance of all transplantation services, including services provided under contract or arrangement.

We proposed requiring a transplant center's QAPI program to use objective measures to evaluate the center's performance with regard to transplant activities and outcomes. We proposed that these activities and outcomes may include, but would not be limited to, patient and donor selection criteria, accuracy of the waiting list in accordance with the OPTN waiting list, accuracy of donor-recipient matching, patient and donor management, techniques for organ recovery, consent practices, patient satisfaction, and patient rights. We proposed that the transplant center must take actions that result in performance improvements and track performance to ensure that improvements are sustained.

We proposed that transplant centers must establish and implement written policies to address and document any adverse events that occur during any phase of an organ transplantation case. We proposed that a transplant center must have policies to address, at a minimum, the process for identification, reporting, analysis, and prevention of adverse events. We also proposed that a transplant center must conduct a thorough analysis of, and document, any adverse event and must utilize the analysis to effect changes in the transplant center's policies and practices to prevent repeat incidents. Following are summaries of the comments we received and our responses.

Comment: Some commenters supported the proposed requirement for a transplant center to have a defined QAPI process. Commenters said the proposed objective measures and adverse events standards were reasonable and would provide impetus for transplant centers to scrutinize and improve performance. A commenter stated that QAPI programs should be quality-driven and not complaint-driven.

Response: We appreciate the commenters' support of the proposed QAPI requirements. We anticipate that transplant centers will take advantage of their own transplant data as well as the wealth of transplant data available

through the OPTN and the SRTR and utilize them effectively to evaluate their own performance and effect positive changes.

Comment: Some commenters stated that the proposed requirement for a transplant center to develop, implement, and maintain a QAPI program would not contribute to improving patient outcomes.

Response: We disagree with the commenters. The effectiveness of QAPI programs in improving the delivery of health care is widely accepted throughout the health care community. An effective QAPI program uses objective data to study and make improvements to all patient care processes on a continuing basis. We expect transplant centers to focus on areas of sub-optimal performance and prioritize outcome measures for improvement. Using this approach, a transplant center can: (1) Identify areas where outcomes indicate a need for improvement; (2) define systematic changes needed to improve outcomes; (3) review implementation of improvement actions; and (4) determine the success of the actions to improve performance.

Comment: Some commenters stated that the QAPI program of a JCAHO accredited hospital and the OPTN oversight of transplant centers should eliminate the need for a separate transplant center-based QAPI program. Some commenters were concerned about the extra resources needed for a transplant center to have a separate QAPI program. Commenters suggested using the OPTN and SRTR as surrogates for transplant centers' QAPI programs. Some commenters recommended that transplant centers should be given the choice of using the hospital QAPI program or establishing a transplant-center-based QAPI program. A few commenters suggested using a formal QAPI program as part of a remediation process for centers that failed to comply with outcome measures.

Response: It is a common practice to use QAPI programs to improve the delivery of health care to patients. The intent of the QAPI requirement in this final rule is to develop a structured process for transplant centers to analyze and evaluate transplant patient outcomes data and transplant center processes continuously and effect changes accordingly. Hospitals have the flexibility to incorporate a transplant center's QAPI program into the hospital QAPI process. However, given the complexity and the uniqueness of some transplant issues, we disagree that a general hospital QAPI program or OPTN oversight alone could adequately substitute for a transplant center-based QAPI program. Further, we disagree that the OPTN and the SRTR should serve as surrogates for transplant centers' QAPI programs. Every transplant center should tailor its QAPI program to meet its needs and its patient population to better serve the best interests of its patients.

Comment: A commenter recommended expanding the components of the QAPI program to include adverse events, electronic prescribing, clinical decision support, bar coding, and provider and patient education.

Response: We thank the commenter for the suggestions. We agree that it is appropriate to include patient education as part of the QAPI components, and we have included this requirement in the regulation text at § 482.96(a) in this final rule.

As we proposed, this final rule includes a separate QAPI standard at § 486.92(b) that requires transplant centers to establish and implement written policies to address and document adverse events. Therefore, we do not believe it is necessary to list adverse events as one of the specific components of a QAPI program at § 482.96(a).

We believe the other components suggested by the commenter belong in the hospital's overall QAPI program because they affect patient care and other functions throughout the organization. Therefore, no other changes have been made based on this comment.

Comment: A few commenters supported the proposed standard for transplant centers to address transplant-related adverse events. A commenter noted that we should specify the frequency of internal and external audits of the adverse events reporting and analysis.

Response: We expect transplant centers to analyze adverse events as they occur and to make systemic and other changes promptly, as necessary, based on their analysis. However, this final rule does not specify the frequency of internal audits or external audits of adverse events. The frequency of adverse events reporting and analysis should be contained in a transplant center's QAPI adverse events policies.

Comment: Some commenters stated that JCAHO survey standards require hospitals to have QAPI policies and sentinel events reporting and investigation. The commenters were concerned that the proposed adverse event standard is redundant and resource-intensive.

Response: As stated earlier, to reduce redundancy, a transplant-oriented QAPI program can be integrated into a hospital's QAPI program for accreditation purposes. Therefore, we do not believe the adverse events requirement, which is one of the QAPI standards in this final rule, will be excessively resource-intensive.

Comment: A few commenters requested the exclusion of non-transplantation-related end-stage organ disease in the adverse events definition.

Response: We did not propose including non-transplantation-related end-stage organ disease in the definition of ''adverse events.'' The examples of adverse events provided in the definition of adverse events in both the proposed rule and this final rule relate only to donation by living donors and to transplantation.

Condition of Participation: Human Resources (Proposed § 482.98)

We proposed that transplant centers must ensure that all individuals who provide services and/or supervise services at the center, including individuals furnishing services under contract or arrangement, are qualified to provide or supervise such services.

We proposed that each transplant center must be under the general supervision of a qualified transplant surgeon or a qualified physician-director with designated responsibilities. We proposed that the director of a transplant center need not serve full-time and may also serve as a center's primary transplant surgeon or transplant physician in accordance with § 482.98(b).

We proposed that the director would be responsible for planning, organizing, conducting and directing the transplant center and must devote sufficient time to carrying out these responsibilities, which include, but are not limited to, ensuring:

(1) Adequate training of nursing staff in the care of transplant patients;

(2) That tissue typing and organ procurement services are available;

(3) That transplantation surgery is performed under the direct supervision of a qualified transplant surgeon in accordance with § 482.98(b).

We proposed that transplant centers must identify to the OPTN both a primary transplant surgeon and a primary transplant physician with the appropriate training and experience to provide transplantation services. We proposed that the transplant surgeon is responsible for providing surgical services related to transplantation, and the transplant physician is responsible

for providing and coordinating transplantation care.

We proposed that transplant centers must have a qualified clinical transplant coordinator to ensure the continuity of care of patients and living donors during the pre-transplant, transplant, and discharge phases of transplantation and the donor evaluation, donation, and discharge phases of donation. We proposed requiring that a qualified clinical transplant coordinator must be certified by the American Board of Transplant Coordinators (ABTC).

We proposed that a transplant center must identify a multidisciplinary transplant team and describe the responsibilities of each member of the team. We also proposed that the team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology.

We proposed that a transplant center must demonstrate the availability of expertise in internal medicine, surgery, anesthesiology, immunology, infectious disease control, pathology, radiology, and blood banking as related to the provision of transplantation services. Following are summaries of the comments we received and our responses.

Comment: Although some commenters supported the proposal that transplant centers must ensure that all individuals providing transplant services are qualified, one commenter stated that transplant centers should have the flexibility to determine their own personnel needs. The commenter voiced concern that the cost of meeting the proposed staffing requirements would increase costs to such an extent that facilities would no longer be able to contract with managed care companies because managed care reimbursement would be insufficient to cover costs.

Response: We believe the staffing requirements in this final rule are critical for the protection of the health and safety of living donors and transplant recipients. Based on public comments, we have eliminated our proposed requirement for ABTC certification for clinical transplant coordinators, and we have added a requirement in this final rule for a living donor advocate or advocate team, which may increase overhead costs for some transplant centers. However, as we discuss in more detail in the Impact Analysis Section of this preamble, we do not expect the donor advocate or donor advocate team requirement in this final rule to increase costs substantially. In fact, we expect an average increase of less than $18,500 per transplant center annually.

Comment: Some commenters stated that the OPTN policies for transplant personnel are industry gold standards and that they should be adopted by us and monitored by the OPTN. One commenter stated that the OPTN and CMS human resources requirements should be consistent.

Response: We believe our requirements are consistent with OPTN policies and bylaws. Section 482.72 of this final rule requires transplant centers to be OPTN members. While the final rule governing the operation of the OPTN does not require transplant programs within OPTN member hospitals that receive their designation by virtue of their Medicare approval to meet the OPTN's on-site primary transplant surgeon and transplant physician requirements, such programs are reviewed by the OPTN, on a voluntary basis, for compliance with such requirements. We expect that transplant centers, as members of the OPTN, will have no difficulty meeting these regulatory requirements, as the OPTN requirements are more extensive than our requirements.

Comment: One commenter suggested that we should add a ''grandfather clause'' for transplant staff to § 482.98, Human resources, as a transition to the new human resources requirements. That is, transplant centers should be permitted to continue to employ their current staff, even if some staff do not meet specific education, training, or licensure requirements in the final rule.

Response: As we stated in our previous response, we expect that transplant centers who are OPTN members will have no difficulty meeting our requirements. Our requirements for transplant surgeons and physicians are congruent with OPTN requirements. Furthermore, we have eliminated the proposed requirement for ABTC certification for transplant coordinators based on public comments, and we replaced it with a requirement for a clinical transplant coordinator to be an RN or clinician licensed in the State in which the coordinator practices and to have specific job-related skills. We expect that all or nearly all currently-employed clinical transplant coordinators already have these qualifications. We are requiring a donor advocate or donor advocate team to have certain knowledge and abilities but not specialized education or training.

Comment: A commenter recommended that we require transplant centers to have a transplant pharmacist on the transplant team.

Response: Section 482.98(e) of this final rule states that the multidisciplinary transplant team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology. Therefore, we expect that the team will include an individual with expertise in transplant pharmacotherapy. We have not made any changes in this final rule based on this comment.

Director of a Transplant Center

Comment: Some commenters supported the proposal that a transplant center be under the general supervision of a qualified transplant surgeon or a qualified transplant physician director. However, one commenter suggested that we clarify the requirements for a qualified director of a transplant center. The commenter suggested that we permit a surgeon or a physician who meets the OPTN requirements for a designated surgeon or physician to be a transplant center director. Other commenters suggested that we cross-reference the OPTN definition for transplant surgeon or transplant physician qualification in the final rule. Some commenters recommended that we require the qualified transplant center director to be a certified surgeon or physician who has completed an approved American Society of Transplant Surgeons (ASTS) training/fellowship and who has been certified for all transplant programs.

Response: We did not define the qualifications for a transplant center director, so that transplant centers will have the flexibility to recruit an OPTN-qualified transplant surgeon or physician for the position. The ASTS training/fellowship is one of the options for transplant surgeons to meet the OPTN training program requirement. However, there are other options surgeons can choose to meet the OPTN training requirement. We do not believe it is necessary to require transplant surgeons to participate in a specific organization's training program to be qualified to provide transplantation services in a Medicare-approved transplant center.

As we have stated in some of our previous responses, we are not incorporating OPTN policies and bylaws into regulations by cross reference because we would be required to go through notice and comment rulemaking every time the policies and bylaws changed. OPTN policies for transplant surgeons and physicians are very detailed and subject to frequent

changes. We believe that such changes will occur too often for us to incorporate them expeditiously into our regulations. We will provide guidance regarding the definitions of qualified transplant center directors, surgeons, and transplant physicians in the Interpretive Guidelines. However, we can assure transplant centers that transplant surgeons and physicians who meet current OPTN requirements will meet the requirements in this final rule.

Comment: One commenter pointed out that nurses do not routinely report to physicians in hospital settings. The commenter suggested that instead of holding the director of a transplant center responsible for ensuring adequate training of nursing staff in the care of transplant patients, we should require the hospital in which the transplant center is located to be responsible for the training of nursing staff.

Response: The commenter was correct in stating that nursing staff do not usually report to physicians in a hospital setting. Therefore, we have modified our proposed language at § 482.98(a)(1) in this final rule, to state that the director of a transplant center must collaborate with the transplant hospital in which the transplant center is located to ensure adequate training of nursing staff and clinical transplant coordinators in the care of transplant patients and living donors.

Transplant Surgeon and Physician

Comment: Some commenters recommended grandfathering all currently active transplant surgeons who have not completed an ASTS fellowship. They also recommended that we require an ASTS fellowship for all new transplant surgeons.

Response: Given that the OPTN gives transplant surgeons different options toward meeting the OPTN qualification requirements, we do not believe a grandfather clause is advisable. As stated previously, the ASTS training/fellowship is just one of the options for transplant surgeons to fulfill the OPTN training program requirements. Requiring all new transplant surgeons to complete an ASTS fellowship would be far too prescriptive and would be inconsistent with the OPTN bylaws.

Availability of Primary Transplant Surgeon and Physician

We received many comments urging us to conform our requirements to the OPTN policies and bylaws for transplant surgeons and physicians, and we believe that we should be consistent with the OPTN rules in this regard. Under OPTN bylaws, a transplant center designated under 42 CFR 121.9(a)(2) must have a primary transplant surgeon and a primary transplant physician onsite at all times. The immediate availability of a transplant surgeon is imperative to minimize time on the waiting list and mortality of transplant candidates. Recently, our surveyors discovered that the inability of a liver transplant center in California to retain a full-time transplant surgeon was a contributing factor to the center's high organ refusal rate, low numbers of transplants, and prolonged waiting time for transplant candidates.

Therefore, under the final rule, we require not only that a transplant center must identify to the OPTN a primary transplant surgeon and a transplant physician with the appropriate training and experience to provide transplantation services as proposed at § 482.98(b), but also that these individuals are immediately available to provide transplantation services when an organ is offered for transplantation. By ''immediately available,'' we mean that the transplant surgeon and transplant physician must be available to provide transplantation services within a time frame that ensures there is no compromise to the viability of the organ or the health of the organ transplant recipient.

Clinical Transplant Coordinator

Comment: Most commenters supported the proposed requirement for a transplant center to have a clinical transplant coordinator.

Response: Clinical transplant coordinators are important links for transplant patients and living donors to transplant centers and dialysis facilities. We believe that clinical transplant coordinators are essential in coordinating the continuity of care of patients and living donors. They provide guidance to transplant recipients during the pre-transplant, transplant, and post-transplant phases and to living donors during the pre-donation, donation and post-donation phases.

Comment: Many commenters supported the proposed requirement for American Board of Transplant Coordinators (ABTC) certification for a qualified clinical transplant coordinator and stated that the ABTC certification would minimize medical errors associated with donation and transplantation. A commenter stated that the ABTC certification is the ''gold standard''.

However, many commenters strongly objected to our proposed requirement for ABTC certification. The commenters said that a requirement for ABTC certification would be arbitrary, given that there are other agencies that certify coordinators. Many transplant center commenters attested that their clinical transplant coordinators are Advance Practice Nurses, have received in-house training, have received continuing education training, or are ABTC-qualified but not ABTC certified, yet they perform their responsibilities well and provide excellent patient care. The commenters suggested accepting sub-specialty certifications, such as critical care or case management, to qualify clinical transplant coordinators.

Some commenters stated that the ABTC requirement would create recruitment hardship, especially for pediatric centers, and eventually raise overhead expenses for transplant centers. A few commenters requested an extension for pediatric centers to meet the ABTC requirement. The commenters noted that pediatric transplant programs usually hire Pediatric Advanced Practice Nurses who then acquire pediatric transplant experience through on-the-job training. Some commenters estimated that it takes about 18 months for a clinical transplant coordinator to become ABTC certified. To ease the difficulty of recruiting ABTC certified transplant coordinators, especially pediatric clinical transplant coordinators, some commenters suggested that we should allow 2 years for a newly-hired transplant coordinator to obtain ABTC certification while he or she continues to work under the supervision of an ABTC-certified coordinator. One commenter suggested requiring ABTC certification for non-RN clinical transplant coordinators while allowing RNs to be certified by credentialing bodies other than the ABTC. Some commenters recommended grandfathering all clinical transplant coordinators with at least 5 years of work experience.

Some commenters did not believe that ABTC certification would improve the care of transplant patients. Other commenters suggested requiring the transplant director to be responsible for ensuring that clinical transplant coordinators receive adequate education and training. Several commenters recommended eliminating the ABTC certification requirement in the final rule.

Response: Since the publication of the proposed rule, we have further examined the education, training, and experience of individuals who serve as clinical transplant coordinators. Although the ABTC certification examination is a valuable avenue to demonstrate transplant knowledge and skill, we found that many clinical transplant coordinators are RNs, clinical

nurse specialists, and nurse practitioners who have acquired transplant knowledge and practice experience in a variety of roles and settings. In recent decades, alternative health care practice models have provided the opportunity for nurses and clinicians to take on an expanded role in transplantation. Therefore, we have concluded that commenters were correct that there is more than one way to acquire the necessary knowledge and skill to be a clinical transplant coordinator. Furthermore, we agree with the commenters that limiting certification to a single organization is not appropriate. Therefore, we have not included a requirement for ABTC certification for transplant coordinators, as we proposed at § 482.98(c).

However, we believe that clinical transplant coordinators should be registered nurses or have clinical experience, and we note that OPTN policies require the clinical transplant coordinator to be either a registered nurse or other licensed clinician. Therefore, in this final rule, we have added a requirement that the clinical transplant coordinator must be either a registered nurse or a clinician licensed by the State in which the clinical transplant coordinator practices, who has experience in and knowledge of, transplantation and living donation issues. (See § 482.98(c).) In addition, this final rule requires that the director of the transplant center must ensure that clinical transplant coordinators have adequate training in the care of transplant patients and living donors. (See § 482.98(a)(1).) Also, we have added language that describes the responsibilities of the clinical transplant coordinator, which include, but are not limited to: (1) Ensuring the coordination of the clinical aspects of transplant patient and living donor care; and (2) acting as a liaison between a kidney transplant center and dialysis facilities, where applicable. (See § 482.98(c).)

Comment: Some commenters asked how many ABTC-certified coordinators are required, that is, whether one coordinator per transplant hospital or organ-specific transplant center is sufficient or whether all coordinators would need to be ABTC certified. A commenter suggested requiring only one ABTC-certified coordinator on site to provide overall supervision to other non-ABTC certified coordinators. A commenter recommended requiring a transplant center to have either an ABTC-certified clinical transplant coordinator or a State-licensed nurse with proficiency in complex professional and administrative transplant skills.

Response: Although this final rule does not require ABTC certification, each organ-specific transplant center must have at least one clinical transplant coordinator who meets the requirements at § 482.98(c) of this final rule. Small transplant centers may share one clinical transplant coordinator.

Donor Advocate or Donor Advocate Team

Comment: The majority of commenters supported our proposed requirement for an independent living donor advocate or a multidisciplinary advocate team. The commenters stated that a living donor advocate or multidisciplinary advocate team can ensure continuity of care of living donors during the pre-donation, donation and post-donation phases.

Only one commenter said that the services of a donor advocate or donor advocate team would not add value to the process of living donation. A few commenters stated that the requirement for a living donor advocacy team would cause hardship for small transplant programs.

Response: We agree with the commenters who said that this requirement will serve the best interests of living donors. We expect that donor advocates and donor advocate teams will educate potential living donors about living donation, ensure that living donors have comprehensive medical and psychosocial evaluations, and make recommendations to the transplant team regarding prospective donors' suitability for donation. The presence of either a living donor advocate or an advocate team will encourage accountability for the protection of living donors' health and safety and ensure that principles of medical ethics and informed consent standards are applied to the practice of living donation.

Under this final rule at § 482.98, we state that a transplant center may choose to have either a living donor advocate or a donor advocate team. These individuals may be in-house hospital staff members who perform other duties in addition to their living donor advocate responsibilities. We believe this flexible approach will minimize the burden of providing donor advocacy services.

Comment: Some commenters stated that transplant centers should be given the flexibility to define their own policies for a living donor advocate program. A few commenters stated that it is unnecessary to require a transplant center to designate a living donor advocate or an advocate team as long as there is an independent process to assess a living donor's risks and the benefits of donation. One commenter suggested that transplant centers should be required only to offer the consulting services of an in-house transplant-educated health care worker not directly involved in transplant procedures.

Response: This final rule provides transplant centers with great flexibility in providing either a living donor advocate or donor advocate team. We do not specify requirements for a donor advocate's background, education, or training or the donor advocate team's composition. Instead, we specify their duties and the skills they must be able to demonstrate, specifically: (1) Knowledge of living organ donation, transplantation, medical ethics, and informed consent; and (2) understanding of the potential impact of family and other external pressures on the prospective living donor's decision whether to donate and the ability to discuss these issues with the donor. The independent living donor advocate or living donor advocate team is responsible for: (1) Representing and advising the donor; (2) protecting and promoting the interests of the donor; and (3) respecting the donor's decision and ensuring that the donor's decision is informed and free from coercion. A transplant center must identify either an independent living donor advocate or an independent living donor advocate team to ensure protection of the rights of living donors and prospective living donors. The living donor advocate or living donor advocate team must not be involved in transplantation activities on a routine basis.

Comment: Many commenters suggested that the donor advocate team should include a qualified social worker as described in the proposed rule or a medical social worker (a social worker working in a medical setting). One commenter suggested that a multidisciplinary advocate team should include an internal medicine physician, a transplant coordinator/nurse clinician, a licensed social worker with a master's degree, a psychiatrist, and an ethicist. Some commenters suggested that either the living donor advocate or advocate team members should be educated in organ transplants.

Response: We appreciate the commenters' suggestions for the composition of the multidisciplinary donor advocate team, and we agree that all the named professionals would be an asset to a donor advocate team. Transplant centers that choose to have a multidisciplinary donor advocate team may want to consider these suggestions in selecting appropriate team members to meet their needs. However, we believe it would be unnecessarily

prescriptive to require that donor advocate teams be composed of individuals from specific professions.

Comment: Many commenters stated that the living donor advocate or the advocate team should be independent from the transplant team. That is, transplant centers should use different physicians and social workers to work with transplant patients and living donors. A commenter stated that it is difficult for a hospital-employed living donor advocate to stay independent.

Response: We agree that the living donor advocate or donor advocate team should function independently from the transplant team to avoid conflicts of interest. Therefore, as stated earlier, this final rule at § 482.98 (d)(1) requires that the living donor advocate or living donor advocate team not be involved routinely in transplantation.

Comment: A commenter suggested that we designate the United Network for Organ Sharing (UNOS) as the gatekeeper for living donor rights and establish an Ombudsman as a resource for all donors nationwide.

Response: UNOS functions as a contractor for the OPTN to collect and track all transplant data, including living donor transplants. CMS does not have the authority to designate UNOS as the gatekeeper for living donor rights. Such suggestions should be referred to UNOS and HRSA. The suggestion that we establish an Ombudsman as a resource for all donors nationwide falls outside the purview of this regulation. Therefore, no changes have been made based on this comment.

Multidisciplinary Transplant Team and Resource Commitment

Comment: A few commenters stated that the OPTN policies already stipulate personnel requirements for transplant centers and that our proposed requirements either duplicated or were inconsistent with OPTN policies.

Response: We proposed that a transplant center must identify a multidisciplinary transplant team and describe the responsibilities of each member of the team. The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology. The OPTN has personnel requirements for certain personnel, such as a clinical transplant coordinator, transplant pharmacist, and financial coordinator. However, the OPTN does not have the transplant team requirements that we proposed and that we have finalized in this rule.

Comment: Many commenters suggested changing the term ''social services'' to ''social work'' (because there is ambiguity about who provides such services), and the term ''pharmacology'' to ''pharmacist'' because not all centers have pharmacologists but all centers have pharmacists.

Response: This final rule requires transplant centers to employ individuals with expertise in different relevant areas. We do not believe the terms ''social services'' or ''pharmacology'' need to be changed or clarified because this standard addresses the expertise of the individual transplant team members, and not the profession of these individuals. We made no changes based on this comment.

Comment: A commenter recommended changing ''immunology'' to ''immunology and immunosuppression management''.

Response: One facet of immunology as a science is the study of organ transplantation and immunosuppression. We expect that to comply with the requirement in this final rule to demonstrate resource commitment in immunology, a transplant center will demonstrate resource commitment and availability of expertise in both immunology and immunosuppression. We have made no changes based on this comment.

Comment: A commenter requested that we require pediatric transplant centers to demonstrate availability of expertise in ''pediatric medicine, pediatric surgery, pediatric urology, pediatric nursing, pediatric dialysis and pediatric intensive care.''

Response: To be in compliance with the requirements in this final rule, a transplant center must provide services appropriate to its patient population. For example, § 482.98(e) requires a transplant center to identify a multidisciplinary transplant team composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology. This means that the individuals who are part of a transplant team at a pediatric transplant center must have the qualifications, training, and experience to provide transplantation services to pediatric patients. Section 482.98(f) requires a transplant center to demonstrate availability of expertise in internal medicine, surgery, anesthesiology, immunology, infectious disease control, pathology, radiology, blood banking, and patient education as related to the provision of transplantation services. To meet this requirement, a pediatric transplant center must ensure that the expertise is commensurate with the needs of pediatric patients. Furthermore, the Department's OPTN regulations at 42 CFR 121.9 require transplant programs in OPTN member hospitals designated under OPTN criteria in § 121.9(a)(2)(v) to show evidence of collaborative involvement with experts in the fields of, among other disciplines, pediatrics as appropriate.

Comment: One commenter anticipated the rule will increase demand for nursing staff and suggested that we should recognize that Advanced Practice Registered Nurses (APRN) can play a role in transplant patient care.

Response: We agree with the commenter that APRNs play an important role in health care. Transplant centers certainly have the discretion to recruit APRNs for their transplant teams as they believe necessary.

Comment: One commenter said that the proposed resource commitment requirements would enhance patient's self-care management and positive patient outcomes. The commenter suggested that we add patient education.

Response: We agree that patient education enhances patient's self-care management and positive patient outcomes. In fact, most transplant centers provide ongoing patient education, which is provided by the transplant center staff, including transplant surgeons, physicians, nurses, transplant coordinators, dietitians, pharmacists, and social workers. We have adopted the comment to include patient education in this final rule as a required resource commitment for transplant centers at § 482.98(f).

Condition of Participation: Organ Procurement (Proposed § 482.100)

We proposed requiring transplant centers to ensure that the hospital in which the center operates has a written agreement for the receipt of organs with an OPO designated by the Secretary.

We proposed that the transplant center would be required to ensure that the transplant hospital's agreement with the OPO identifies specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation.

We proposed that the transplant center must notify us in writing no later than 30 days after the termination of any agreement between the hospital and the OPO. Following is a summary of the comments we received on our proposed

provisions and our responses to the comments.

Comment: A commenter stated that the proposed organ procurement provision is duplicative of 42 CFR 121.9(a)(2)(i).

Response: The commenter was correct in identifying similarities between this provision and the designated transplant program requirements in the Department's regulations for the OPTN at 42 CFR 121.9(a)(2)(i). Including the organ procurement requirements in this final rule provides us with oversight and enforcement authority and imposes the requirements on transplant programs that received their designation by virtue of their approval for reimbursement for Medicare.

Comment: A few commenters suggested requiring a center to notify the OPTN if its hospital's agreement with an OPO has been terminated.

Response: We do not believe terminating an agreement with an OPO is a step a hospital would take without the knowledge of the OPTN. Thus, we do not believe it is necessary for us to require a transplant center to notify the OPTN if the hospital in which it is located terminates its agreement with an OPO. We have made no change in this final rule based on this comment.

Note that for the sake of consistency and to facilitate transplant centers' use of the regulations, we have moved the requirement to notify us if the hospital in which a transplant center is located terminates its agreement with an OPO for organ recovery and receipt from § 482.100 to § 482.74(a)(3), Notification to CMS. This change locates all events that must be reported to us within the same condition of participation and results in consistent time frames for notification. The requirement for notifying us if the hospital in which a transplant center is located terminates its agreement with an OPO for organ recovery and receipt is changed from 30 days to ''immediately,'' to facilitate monitoring of waiting list patients' access to organs.

Condition of Participation: Patient and Living Donor Rights (Proposed § 482.102)

In our discussion of patient rights in the preamble to the proposed rule, we said that we believed a living donor advocate or advocate team would ensure that the informed consent standards meet ethical principles as applied to the practice of living donor organ transplantation. Thus, we requested comments on whether we should include a requirement in the final rule for transplant centers performing living donor transplants to provide the services of an independent living donor advocate or advocate team, as well as recommendations for individual or team credentials. Based on public comments, we have added a requirement in this final rule, at § 482.98(d) CoP: Human resources, for an independent living donor advocate or living donor advocate team. The preamble discussion of an independent living donor advocate or living donor advocate team is located under the Human resources section of this final rule.

We proposed that in addition to meeting the general hospital requirements for patients' rights in the hospital CoPs at § 482.13, a transplant center must protect and promote each transplant patient's and living donor's rights.

We proposed that the transplant center must have a written informed transplant patient consent process that informs each patient of: (1) The evaluation process; (2) the surgical procedure; (3) alternative treatments; (4) potential medical and psychosocial risks; (5) national and transplant center-specific outcomes; (6) the fact that future health problems related to the transplantation may not be covered by the recipient's insurance and that the recipient's ability to obtain health, disability, or life insurance may be affected; (7) organ donor risk factors that could affect the success of the graft or the health of the patient, including, but not limited to, the donor's history, condition or age of the organs used or the patient's potential risk of contracting the human immunodeficiency virus and other infectious diseases if the disease cannot be detected in an infected donor; and (8) his or her right to refuse transplantation.

We proposed that transplant centers must implement a written living donor informed consent process that informs prospective living donors of all aspects of living donation and potential outcomes from living donation. We proposed that transplant centers must ensure that prospective living donors are fully informed about the following: (1) The fact that communication between the donor and the transplant center will remain confidential in accordance with the requirements at 45 CFR parts 160 and 164; (2) the evaluation process; (3) the surgical procedure, including post-operative treatment; (4) availability of alternative treatments for the transplant recipient; (5) potential medical and psychosocial risks to the donor; (6) national and transplant center-specific outcomes for both donors and recipients; (7) the possibility that future health problems related to the donation may not be covered by the donor's insurance, and that the donor's ability to obtain health, disability, or life insurance may be affected; and(8) the donor's right to opt out of donation at any time during the donation process.

We proposed that a transplant center must notify its waiting list patients of information about the center that could impact the patient's ability to receive a transplant should an organ become available, and the procedures that are in place to ensure the availability of a transplant team.

We proposed that a transplant center served by a single transplant surgeon or physician would be required to inform its waiting list patients of the potential unavailability of the transplant surgeon or physician and whether the center had a mechanism to provide an alternate transplant surgeon or transplant physician that meets the hospital's credentialing policies.

We proposed that at least 30 days before a center's Medicare approval was terminated, whether voluntarily or involuntarily, the center would have to inform the patients on the waiting list of this fact, and must provide assistance to patients who choose to transfer to another Medicare-approved center, without loss of the patient's time accrued on the waiting list.

We also proposed that if a transplant center were terminated, such transplant center would have to inform Medicare beneficiaries on the center's waiting list that Medicare would no longer pay for transplants performed at the center after the effective date of the center's loss of approval.

We requested comments on the proposed requirement for a transplant center to inform patients of potential organ donor risk factors that could affect the success of the graft or the health of the patient, including, but not limited to, the donor's history; condition or age of the organs used; or the patient's possible risk of contracting the human immunodeficiency virus and other infectious diseases if the disease could not be detected in an infected donor. We also solicited comments regarding our proposed informed consent requirements for living donors, including those requirements we proposed adopting from the Secretary's Advisory Committee on Transplantation (ACOT) recommendations, and whether we would need to establish additional criteria for transplant centers performing living donor transplants.

Following are summaries of the comments we received and our responses.

Comment: Some commenters said that all kidney transplant centers should be

exempt from initial approval requirements (such as the requirement to perform 9 transplants) because a lengthy initial approval process would delay access to the new kidney center's transplantation services for Medicare beneficiaries.

Response: We share the commenters' concern that a lengthy approval process for kidney centers, particularly a requirement to perform 10 transplants prior to approval, may disadvantage Medicare beneficiaries who need kidney transplants by limiting their access to transplantation services at new kidney transplant centers. Under section 1861(s)(2)(J) of the Act, almost all ESRD transplant candidates must have their transplant surgery and follow-up care provided by a center that is already Medicare-certified in order for their immunosuppressant drugs to be paid for under Part B of Medicare as part of the Medicare transplantation services. Therefore, we are concerned that some new kidney centers may offer to provide free kidney transplants to Medicare beneficiaries in order to meet the Medicare clinical experience requirements and thus obtain Medicare approval expeditiously. These prospective kidney transplant candidates may not be aware of the implications for such free transplants that Medicare only pays for prescription drugs used in immunosuppressive therapy under Medicare Part B if the transplant was performed in a Medicare-approved facility.

Therefore, we have added a requirement under the CoP for Patient and Living Donor Rights at §§ 482.102(a)(8) and 482.102(b)(9) that a transplant center must inform Medicare beneficiaries who are prospective transplant recipients and their living donors that receiving a transplant that is not provided in a Medicare-approved transplant center could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid for under Medicare Part B. See further discussion of this requirement in this preamble under ''Centers With Current Medicare Approval.''

Comment: A commenter recommended that the OPTN incorporate ACOT recommendations on transplant patient and living donor rights into its policies and monitor transplant center compliance. Another commenter suggested that we or the OPTN should provide transplant centers with sample education materials to educate donors about their rights.

Response: The OPTN has published a variety of transplant education brochures for centers to distribute to patients and living donors; the list of resources is available at *www.transplantliving.org*. Although the OPTN does not have any publications specific to living donation (with the exception of some limited information published in the booklet titled ''What Every Patient Needs to Know'') it has posted extensive living donation information on its Web site. Suggestions that the OPTN adopt ACOT recommendations are beyond the scope of this rule.

Informed Consent

We are removing the proposed requirement that transplant centers inform transplant candidates of ''the fact that future health problems related to the transplantation may not be covered by the recipient's insurance, and that the recipient's ability to obtain health, disability, or life insurance may be affected.'' This language was included in the proposed rule in the standard for informed consent for transplant patients at § 482.102(a)(6); similar language was included in the standard for informed consent for living donors at § 482.102(b)(7). It was intended to apply only to living donors. Thus, it has been removed at § 482.102(a)(6).

Comment: Many commenters supported the requirement for informed consent to protect patient rights. However, some commenters supported the adoption of the ACOT recommendations in their entirety, rather than the limited number of specific informed consent elements that we proposed. One commenter recommended that we require a standardized informed consent process for all transplant centers.

Response: We have chosen not to adopt the ACOT recommendations in their entirety because they are extensively detailed and go beyond what we perceive as necessary for Medicare approval. Instead, we have adopted the ACOT recommendations that are directly related to transplant patient and living donor rights. We have not included other recommendations that address organ donation, organ allocation, and organ procurement organizations. This final rule does not require a standardized informed consent process because such a requirement would deprive transplant centers of the flexibility we believe they need to develop informed consent policies that best serve their needs.

Comment: A few commenters stated that the proposed informed consent provisions for transplant patients and living donors are too prescriptive and not a standard practice in medicine. The commenters said that a transplant center's only legal obligation is to provide patients and living donors with sufficient information to make an informed decision. A few commenters said that the requirement for a written informed consent process is burdensome and unnecessary since hospitals already have informed consent policies that may be applicable to transplants.

Response: As a standard practice for any type of surgical procedure, a hospital has the obligation to provide patients with sufficient information to make informed decisions. We believe the elements of informed consent that we proposed and that we require under this final rule are the minimum necessary to ensure transplant patients and living donors can make an informed decision. (See § 482.102(a).) We believe this basic information should be provided to patients and living donors by all transplant centers.

We recognize that a transplant center's informed consent process may overlap with the hospital's informed consent process. A transplant center may choose to integrate the required elements for the transplant center informed consent process into the hospital informed consent process. We note, however, that transplant patients and living donors are uniquely vulnerable patients. Prospective transplant recipients desperately need scarce, life-saving organs, and many of them will die waiting. Prospective living donors are healthy individuals who are contemplating undergoing surgery, at some risk to themselves, to provide a life-saving transplant to another individual. These patients and prospective living donors must absorb a great deal of information in order to provide a truly informed consent.

In their recommendation, ACOT endorsed two ethical principles: (1) Equipoise; that is, the benefits to both the donor and the recipient outweigh the risks associated with the donation and transplantation of the live donor organ; and (2) that the potential donor's participation is completely voluntary and may be withdrawn at any time. We believe transplant centers should base their informed consent policies and procedures on these principles and implement them scrupulously. We made no changes based on these comments.

Comment: A commenter stated that once a transplant center documents in medical records that a patient's informed consent was obtained (including the specifics that were discussed), it should be sufficient evidence that an informed consent policy exists.

Response: We disagree. We expect a transplant center to have informed consent policies that include a written informed consent process and documentation that informed consent was given. Therefore, the documentation of informed consent alone would not be sufficient to substitute for a written informed consent policy.

Comment: Some commenters suggested eliminating the prescriptive informed consent language. One commenter stated that the requirement for a transplant center to inform patients about the patient evaluation process is too prescriptive.

Response: We believe the information in the elements of informed consent that we proposed and that are set forth in this final rule are necessary for patients to make an informed decision about transplantation. We also believe it is important for transplant candidates to understand how they will be evaluated for placement on the waiting list, how their readiness for transplant will be ascertained while they are awaiting transplantation (for example, through periodic blood tests), and what factors could require their removal from the waiting list.

Comment: Some commenters said that a transplant center should be required to use a patient education checklist to educate patients about transplant risks. One commenter asked how patient informed consent should be documented to comply with this requirement.

Response: A transplant center may use any patient education tools, such as a patient education checklist, to educate patients about transplant risks, as long as the center includes the required elements. A transplant center may choose to document the discussion of informed consent in any format as long as the discussion is documented in the patient's medical record.

Comment: One commenter stated that a last-minute discussion of potential donor risk with a transplant recipient would be extremely difficult because the window of time between organ procurement and transplantation is very short. The commenter said that it is unrealistic to require centers to repeat the extensive informed consent process at the time of transplantation and suggested that the discussion with transplant candidates about potential risks should be done well before an actual organ offer takes place. The commenter recommended that the informed consent process be limited to the point in time when a patient is placed on a transplant waiting list.

Response: We agree with the commenter. Our expectation is that discussion of potential donor risk factors should occur well before an organ is offered, for example, when the patient is first placed on the waiting list, and the information should be reviewed with the patient from time to time. We agree with the commenters that the time period between organ procurement and the offer of an organ may be too short for a thorough discussion of informed consent with patients. We do not expect a transplant center to rush through a detailed discussion of potential donor risk factors with transplant candidates just prior to transplantation.

Comment: Some commenters expressed concern that it could be impossible for transplant centers to discuss all potential organ donor risk factors with transplant candidates. Another commenter stated that requiring a transplant center to provide a written explanation of organ-specific risk factors to patients would be burdensome.

Response: Although it may not be possible for transplant centers to discuss every single potential organ donor risk factor with patients on their waiting lists, we expect centers to cover, at a minimum, the factors listed in the text of this final rule, that is, donor history; condition or age of the organs used; and the patient's risk of contracting the human immunodeficiency virus and other infectious diseases if the disease cannot be detected in an infected donor. Providing this information should ensure that patients understand before they make transplant decisions that certain factors may affect the success of their transplant. Transplant centers certainly have the flexibility to discuss other risk factors beyond those we have delineated in this final rule.

The requirement for transplant centers to have a written informed consent process does not mean that centers must provide a written explanation of organ-specific risk factors to transplant patients. As proposed, this final rule requires only that a transplant center inform patients of organ and organ donor risk factors.

Comment: A commenter recommended that we require transplant centers to provide some minimal information for patients contemplating acceptance of an extended criteria donor (ECD) kidney as follows: (1) The increased likelihood of delayed graft function; (2) decreased graft survival compared to a non-ECD kidney; (3) increased longevity compared to remaining on dialysis; (4) the potential for decreased waiting time for a donated kidney; and (5) the benefit of receiving a transplant prior to beginning dialysis, which may cause related morbidity and mortality.

Response: We agree with the commenter that these factors should be discussed with patients contemplating acceptance of an ECD kidney. As discussed in our previous comment, the fact that transplantation of certain types of organs (such as ECD or DCD organs) may have an effect on patient or graft survival must be discussed with transplant candidates, as appropriate. Thus, if a kidney transplant center transplants organs from ECDs, they should include all relevant facts about ECD organs in their discussion of organ donor risk factors with patients who are candidates for transplantation with an ECD organ, especially information about patient morbidity and mortality on dialysis versus transplantation with an ECD organ.

Comment: A commenter suggested letting the transplant surgeon decide based on OPTN guidelines whether the organ donor risk factors are significant enough to warrant a discussion with a patient.

Response: We agree with the commenter that the transplant surgeon should be responsible for taking the lead in discussing potential organ donor risk factors with the patient. At a minimum, we expect the transplant surgeon to discuss the potential organ donor risk factors described at § 482.102(a). The transplant surgeon also should decide whether other factors should be discussed. Although currently, there are no universal guidelines for organ donor risk factors, we believe surgeons should be able to reference current practices in their discussions with patients.

Comment: Some commenters objected to the proposed requirement to inform patients of national and center-specific transplantation outcomes, as indicated in the SRTR reports. The commenters stated that expected survival rates indicated in the SRTR do not reflect the potential compromise of outcomes resulting from the use of ECD/DCD organs by some centers.

In addition, the commenters were concerned that some patients may not have adequate knowledge to interpret the expected survival data properly.

Response: The national and center-specific outcomes as indicated in the SRTR reports are already publicly available at *http://www.ustransplant.org*. The SRTR has added ECD as one of the risk-adjustment factors used in calculating expected survival rates. The OPTN may consider including DCD organs as one of the risk-adjustment factors when more data are available.

Some patients may not be able to fully comprehend the SRTR reports. Nonetheless, we expect a transplant center to provide guidance to patients and families in finding and interpreting the SRTR reports in relation to the center's own patient outcomes. At a minimum, we expect a transplant center to provide prospective transplant recipients, their families, and prospective living donors with information from the most recent SRTR center-specific report, including (but not limited to) the transplant center's observed and expected 1-year patient and graft survival, national 1-year patient and graft survival, and notification about all Medicare outcome requirements not being met by the transplant center.

Comment: Many commenters supported establishing requirements for an informed consent process for living donors. Some commenters noted that informed consent for living donors protects the donor and reduces legal liability for the transplant team. Many commenters said that they specifically supported incorporating the ACOT recommendations into Medicare requirements. In fact, one commenter was concerned that we had not adopted all of ACOT's initial recommendations related to living donation.

Response: We agree that protections for living donors are essential. Therefore, as proposed, we are adopting the ACOT recommendations that address the health and safety of living donors.

Although we have not adopted the ACOT recommendations for living donors in this final rule in their entirety, because some of them fall outside the purview of this rule, we recommend that transplant centers that perform living donor transplants consider them when developing informed consent policies for living donors.

Comment: A commenter stated that there is no compelling reason why the proposed informed consent process for living donors should go beyond the OPTN requirements.

Response: Currently, the OPTN Living Donor Committee workgroup has identified living donor safety promotion as a major focus of the OPTN. However, standardized OPTN informed consent language for living donors has yet to be developed. In light of the fact that living donation is becoming more common, there is an increasing need to protect the health and safety of living donors. Further, as we have stated in our responses to previous comments including these requirements in regulations provides us with the authority for oversight and enforcement.

Comment: A commenter stated that the requirement for transplant centers to model the ACOT recommendations for informed consent for living liver donors is overbearing and noted that it should not apply to living kidney donors as living kidney donation is a more simplified procedure requiring fewer informed consent details.

Response: We did not propose requiring hospitals to adopt the ACOT recommendations for informed consent for living liver or kidney donors. We cited the documents in the preamble to the proposed rule only to provide guidance for transplant centers developing informed consent polices for living donors. However, all living donors deserve the same level of protection. Although individuals contemplating living donation of different organ types may need different information, all living donors should be provided with sufficient information on which to make a fully informed decision.

Comment: A commenter requested clarification on the requirement for documentation of informed consent for living donors, and the commenter asked if separate informed consent forms are needed for living donors.

Response: A transplant center may choose to document the discussion of informed consent with living donors in any manner it chooses. The center may document every discussion in detail or use a checklist or any other tool of its choice to indicate that all the core components were covered. We expect that transplant centers will use different informed consent forms for living donors since the informed consent components are slightly different than for transplant recipients.

Comment: A commenter noted that the presentation of the elements of informed consent to potential recipients and living donors should be easy to understand and consistent with each patient's native language and educational level. The commenter said that adequate time should be given to donors to make a donation decision that is free from coercion and noted that New York State law gives living donors 2 weeks to make a decision.

Response: We agree with the commenter's observations. Nevertheless, we have not specified requirements in this final rule for educational level or language for informed consent documents, nor have we specified a standard period of time prospective living donors be given to make a donation decision. We have avoided such prescriptive requirements throughout this final rule to provide transplant centers with the maximum flexibility to implement the rule's requirements according to their needs and the needs of their patient populations. Although we have not incorporated the commenter's suggestions into this final rule, we would urge transplant centers to consider the suggestions as they develop their informed consent process.

Comment: Some commenters supported the concept of informing living donors of short and long-term risks but suggested eliminating the requirement because providing this information would require the availability of a living donor registry that tracks these risks. A commenter recommended that the Secretary pursue action to establish a living donor registry.

Response: Currently, there is no official living donor registry. However, collection of living donor outcome metrics by the OPTN is ongoing, and the follow-up data period for live donors has been extended from 1 year to 2 years post-transplant. The OPTN is re-evaluating living donor follow-up forms, developing strategies to improve their completeness, and considering the development of a living donor registry. Once data for national and transplant center-specific outcomes for living donors are readily available to transplant centers, centers must begin providing the data to living donors to assist them in making a decision whether to donate. In the interim, each center must provide whatever data are available on its own living donor outcomes to prospective living donors. Should national living donor data become available in the future, transplant centers must provide this information to prospective living donors. Thus, we have added language at § 482.102(b)(6) that specifies living donors must be informed about national and center-specific outcomes for living donors, as data are available.

Notification to Patients

Note that we have removed the phrase ''that meets the hospital's credentialing policies'' from the end of the sentence ''whether or not the center has a mechanism to provide an alternate transplant surgeon or transplant physician that meets the hospital's credentialing policies'' in § 482.102(c)(1)(ii) of the proposed rule. A hospital where a transplant center is located should have a process for credentialing of its staff as required by § 482.22. Therefore, a requirement for an alternate transplant surgeon or transplant physician ''that meets the hospital's credentialing policies'' is unnecessary.

Comment: Some commenters supported the requirement for a transplant center to notify patients of information that could impact the patients' ability to receive an organ. Such information would include informing patients of the possibility that a center's sole transplant team might be unavailable when an organ becomes available and whether the center has a mechanism to provide an alternate transplant surgeon or transplant physician. However, other commenters said that the requirement would be burdensome. They stated that a requirement to notify patients about short-term absences (for example, sickness, vacation, and conferences) would be unrealistic. The commenters suggested that a requirement to notify waiting list patients of the unavailability of the transplant surgeon or physician for more than 30 days would be realistic.

Response: We did not propose nor do we require in this final rule that transplant centers notify waiting list patients about specific absences as they occur. Instead, we are requiring a transplant center served by a single transplant surgeon or physician to inform each waiting list patient of the possibility that the center's transplant surgeon(s) or physician(s) may not be available at the time an organ becomes available. We also require a transplant center to tell each waiting list patient whether the center has a mechanism to provide an alternate transplant surgeon or physician.

Comment: A commenter suggested that in the context of termination under § 482.102(c)(2), which requires a transplant center whose Medicare approval is terminated to inform waiting list patients at least 30 days prior to the termination, we should modify the 30-day requirement by adding ''and following the exhaustion of all appeals provided pursuant to [part] 498 * * *.''

Response: The general provisions under 42 CFR part 498 provide for an administrative judicial review of administrative determinations, for providers facing termination of Medicare approval. Thus, if a transplant center appeals a termination of Medicare approval under 42 CFR, part 498, the termination will not occur until the appeals process, if any, is completed. Therefore, there is no need to incorporate the commenter's suggested language.

Comment: A commenter stated that the proposed rule does not address how care would be provided for patients on the waiting list of a transplant center whose Medicare approval was terminated.

Response: We disagree. Sections 482.102(c)(2)(i) and (ii) of both the proposed rule and this final rule provide that at least 30 days before a center's Medicare approval is terminated, whether voluntarily or involuntarily, the center must inform patients on the center's waiting list. The transplant center also must provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list. Further, the transplant center must inform Medicare beneficiaries on the center's waiting list that Medicare will no longer pay for transplants performed at the center after the effective date of the center's loss of Medicare approval.

This final rule adds a requirement at § 482.102(c)(3) for patient notification if a transplant center voluntarily inactivates. We require that as soon as possible, prior to a transplant center's inactivation, the center must inform patients on the center's waiting list and, as directed by the Secretary, provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list. As we stated earlier, we intend to monitor transplant center inactivity closely.

Condition of Participation: Additional Requirements for Kidney Transplant Centers (Proposed § 482.104)

We proposed to delete some sections from part 405, subpart U and move some of the sections in subpart U to this final rule.

We proposed that kidney transplant centers be required to furnish: (a) Transplantation and other medical and surgical specialty services required for the care of ESRD patients; and (b) inpatient dialysis services, directly or under arrangement. We proposed that such kidney dialysis centers or units must meet the conditions for coverage of suppliers of ESRD services contained in part 405, subpart U.

We proposed that kidney transplant centers would be required to cooperate with the ESRD Network designated for its geographic area in fulfilling the terms of the network's current statement of work.

Following are summaries of the comments we received and our responses. Note that based on public comments summarized earlier in this preamble, we have added a requirement at § 482.104(a) that a kidney transplant center must have written policies and procedures for ongoing communication with dialysis patients' local dialysis facilities.

Comment: A commenter requested clarification about the extent to which a dialysis facility providing acute services to transplant recipients must meet the requirements of a chronic dialysis facility under the ESRD rule. Another commenter suggested deleting the proposed requirement for transplant centers that furnish inpatient dialysis services to meet the conditions for coverage for suppliers of ESRD Services contained in part 405 Subpart U. A commenter recommended that we add a new condition of participation for inpatient dialysis units to provide regulatory guidance for providers of inpatient dialysis services in acute care settings.

Response: Based on these comments and further analysis of our proposal, we have concluded that it is unnecessary to require transplant centers that provide inpatient dialysis services to kidney transplant patients to comply with the Conditions for Coverage for Suppliers of ESRD Services in part 405 subpart U. Kidney transplant centers are located inside hospitals that must comply with the Medicare hospital CoPs, which include quality standards that apply to all services provided by hospitals. Since inpatient dialysis services furnished either directly by kidney transplant centers or under arrangement are subject to the requirements in the hospital CoPs, we see no need to regulate inpatient dialysis services separately.

Therefore, we have removed the proposed requirement at § 482.104(b) that inpatient kidney dialysis centers or units must meet the Conditions for Coverage, part 405, subpart U for suppliers of ESRD services. We have retained in this final rule only the requirement that kidney transplant centers must furnish inpatient dialysis services directly or under arrangement. However, a kidney transplant center that furnishes outpatient dialysis services directly or under arrangement in dialysis centers or units is required to meet the Conditions for Coverage for Suppliers of ESRD Services contained in part 405, subpart U.

Comment: A commenter suggested requiring transplant centers performing pediatric kidney transplants to provide inpatient pediatric dialysis services with appropriate pediatric equipment and nursing expertise.

Response: We expect both pediatric and adult transplant centers to provide staffing, equipment, and other resources appropriate to the needs of their specific patient population. Since providing inpatient dialysis services to pediatric patients may require specialized

pediatric equipment and specific pediatric nursing expertise, we believe transplant centers should have the flexibility to determine how they will provide these services. We have made no changes in this final rule based on this comment.

Comment: A few commenters supported the requirement for kidney transplant centers to remain associated with the ESRD Network. However, one commenter stated that the proposed requirement for participation in network activities is duplicative of 42 CFR part 405, subpart U and requested clarification.

Response: Existing §§ 405.2110 through 405.2112 contain provisions that relate to the designation and functions of the ESRD networks. These provisions focus primarily on the role and responsibilities of the ESRD networks. Although we do not believe the role and responsibilities of the networks need to be included in this final rule, we believe that kidney transplant centers must continue to share information and collaborate with the networks. Thus, under § 482.104(c), we are finalizing our proposal that kidney transplant centers must cooperate with the ESRD network designated for their geographical area in fulfilling the terms of the network's current statement of work.

Deeming Authority (§ 488.6)

Under § 1865 of the Act and § 488.5 of the regulations, hospitals that are accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the American Osteopathic Association (AOA) are not routinely surveyed by the State survey agencies for compliance with the CoPs. Instead, they are deemed to meet the requirements based on either their JCAHO or AOA accreditation. In order to receive this deemed status, hospitals as well as other providers and suppliers, which are accredited by JCAHO, AOA, or other national accreditation programs with deeming authority under § 488.6 of the regulations (see part 488, Survey and Certification Procedures), must meet requirements that are at least as stringent as the Medicare CoPs. Therefore, an accreditation organization could apply for and receive approval of deeming authority for the transplant center CoPs if the accreditation organization demonstrates that its requirements for transplant centers are at least as stringent as those in this final rule. In this final rule, we are amending § 488.6, as described at 42 CFR part 488, subpart A, to include transplant centers, except for kidney transplant centers, among those providers and suppliers that are eligible to receive deemed status based on such an accreditation. A transplant center can choose to meet the requirements through the accreditation process or through a State survey. As a designee of CMS, an accrediting organization or a State survey agency must survey each transplant center's compliance with the clinical experience, outcome, data submission, and process requirements. In either case, the special procedures for transplant centers, as described under § 488.61, will ultimately guide the survey process.

Special Procedures for Approval and Re-Approval of Organ Transplant Centers (Proposed § 488.61)

We proposed utilizing the survey, certification, and enforcement procedures described at 42 CFR part 488, subpart A, including the periodic review of compliance and approval contained in § 488.20. We would retain § 488.60 to apply exclusively to ESRD facilities. Following are summaries of the comments we received and our responses.

(a) Initial Approval Procedures

We proposed that a transplant center would be permitted to submit a letter of request to us for Medicare approval at any time. We proposed that the letter, signed by a person authorized to represent the center, would have to include the hospital's Medicare provider I.D. number, name(s) of the designated primary transplant surgeon and primary physician, and a statement from the OPTN that the center had complied with all data submission requirements.

We proposed that we or our designee would determine a transplant center's compliance with the data submission and outcome requirements proposed at § 482.80(b) and (c). We or our designee would review the 1-year patient and graft survival data contained in the SRTR's most recent center-specific reports.

We proposed that, if both of the conditions in § 482.80(b)(4) applied, the center could ask the SRTR to prepare a customized report of the center's 1-month patient and graft survival data for the previous 1-year period. We or our designee would determine compliance with the outcome requirements contained at § 482.80(b) using the data contained in these customized reports.

We proposed that if we or our designee determined that a transplant center met the data submission and outcome requirements of § 482.80, we or our designee would conduct a survey and review the center's compliance with the conditions of participation contained at § 482.68 through § 482.76 and § 482.90 through § 482.104, using the procedures described at 42 CFR part 488, subpart A.

We proposed that if a transplant center seeking Medicare approval was found to be in compliance with all conditions of participation at § 482.68 through § 482.104, except for § 482.82 (Re-approval requirements), we would notify the transplant center in writing of the effective date of its Medicare approval or notify the transplant center in writing if it were not approved. We proposed that we would grant initial approval to a transplant center for 3 years.

(b) Re-Approval Procedures

We proposed that once Medicare-approved, a transplant center would have to be in compliance with all conditions of participation for transplant centers at § 482.68 through § 482.104, except for § 482.80 (Initial approval requirements) throughout the 3-year approval period.

We proposed that at least 180 days before the end of the 3-year approval period, we or our designee would review the transplant center's data in making re-approval determinations.

We proposed that: (1) To determine compliance with the data submission requirements at § 482.82(a), we or our designee would request data submission data from the OPTN for the previous 3 calendar years; and (2) to determine compliance with the outcome requirements at § 482.82(c), we or our designee would review the data contained in the most recent SRTR center-specific reports.

We proposed that if we or our designee determined that a transplant center met the data submission and outcome requirements at § 482.82, the transplant center would be re-approved for 3 years.

We proposed that if we or our designee determined that a transplant center failed to meet the data submission or outcome requirements contained at § 482.82, the transplant center would be surveyed for compliance with § 482.68 through § 482.76 and § 482.90 through § 482.104, using the procedures described at 42 CFR part 488, subpart A.

We proposed that we or our designee would notify the transplant center in writing if it were re-approved or if its approval were being revoked. If re-approved, we or our designee would notify the transplant center of the effective date of the re-approval.

(c) Loss of Medicare Approval

We proposed that centers that lost their Medicare approval would be permitted to seek re-entry into the program at any time, using the procedures described at § 488.61(a). We proposed that a center that lost its Medicare approval would be required to be in compliance with §§ 482.68 through 482.104, except for § 482.82 (Re-approval procedures), at the time of the request for Medicare approval. We proposed that a center seeking to re-enter the Medicare program would be required to submit a report documenting any changes or corrective actions the center took as a result of the loss of its Medicare approval status.

We proposed that transplant centers with current Medicare approval would be permitted to continue to provide transplant services until we notified them whether they were approved under the new CoPs for transplant centers. For clarity we are adding the words ''OPTN Data Report'' to the regulation text for this section to describe the source of the data we will review to determine compliance with the clinical experience requirements. Following are summaries of the comments we received and our responses.

Initial Approval Procedures for New Transplant Centers

Comment: Some commenters disagreed with the proposed process for initial approval of transplant centers, specifically, that if a center did not meet the data submission and/or outcome requirements, the center would not be considered for approval. Some commenters stated that data submission and outcome measures should be used only as indicators and not as pass/fail tests to approve centers. Other commenters suggested that the initial approval procedures should be similar to the proposed re-approval procedures, so that centers failing to meet the data and outcome requirements would not be denied Medicare approval automatically but would be surveyed to determine whether they should be approved.

Response: In view of the public comments, as well as the potential disruption for Medicare beneficiaries if a large number of currently approved centers are denied initial approval under the requirements of this final rule, we will not deny initial approval to a transplant center automatically as we proposed at § 488.61, if it fails to meet the data, clinical experience, or outcome requirements at § 482.80. Instead, we will take a flexible approach to our initial approval of transplant centers, as described at § 488.61 in this final rule. For the initial approval process, we will conduct a follow-up survey in all instances at currently Medicare-approved transplant centers if the center has not met the clinical experience and/or outcome requirements. We will exercise our discretion for new applications to the Medicare program. CMS will prioritize the scheduling of follow-up surveys based on the center's volume and outcome measurements and the program's history. CMS will survey these centers for the remaining conditions of participation and develop plans of correction for any condition or standard that is not met. If a center has ''failed'' the outcome measures, we will expect the plans of correction to include steps to improve these outcomes within a reasonable time frame (for example, by the next release of outcomes in the center-specific report).

Thus, under this final rule at 488.61(a)(3), if we determine that a transplant center, including a kidney transplant center, applying for initial approval has not met the data submission, clinical experience, or outcome requirements, we may deny the request for approval or we may review the center's compliance with the conditions of participation at § 482.72 through § 482.76 and § 482.90 through § 482.104, using the procedures described at 42 CFR part 488, subpart A, to determine whether the center's request should be approved. Our review may include a survey of the transplant center. We will notify the transplant center in writing whether its request has been approved and, if approved, the effective date of its approval.

However, we will not grant initial approval unless: (1) The center has met or has come very close to meeting the data, clinical experience, and outcome requirements; and (2) the center is in compliance with all other conditions of participation. In the initial approval process, we will give the center an opportunity to correct any areas that do not meet the Conditions of Participation in a reasonable time period through a Plan of Correction that is developed by the Center, and approved and monitored by CMS.

Following are examples of situations in which a transplant center applying for initial approval fails to meet the data submission, clinical experience, or outcome requirements and, for each example, an explanation of why we would or would not approve the center.

Example 1: A large heart transplant center that is currently Medicare approved under the NCDs applies for initial approval under the new CoPs. The center consistently performs a large number of heart transplants annually and demonstrates superior performance on the outcome requirements. However, the transplant center has not met the data submission requirement by submitting 95 percent of the required data to the OPTN within 90 days of the due date. In fact, in the preceding 12 months, the transplant center submitted less than 90 percent of its transplant data within 90 days of the due date.

Because of the transplant center's extensive clinical experience and superior outcomes, we perform a review of the center and determine that the center meets all conditions of participation other than the standard for data submission. The transplant center submits a plan of correction to us, demonstrating how it plans to come into compliance with the data submission requirement by hiring additional staff to collect transplant data and report it to the OPTN. We review and accept the plan of correction and approve the center.

Example 2: A small, currently-approved liver transplant center applies for initial approval under the new CoPs. The center is the only liver center in a large western state that is primarily rural. The center meets the data submission requirement and its outcomes are acceptable. However, the center performed only 7 transplants in the preceding 12 months. Because the transplant center meets the data submission and outcome requirements and because it is the only liver transplant center in a largely rural state, we perform a review of the center and determine that it meets all the standards other than the clinical experience requirement. The center submits a plan of correction, detailing how it will attempt to meet the clinical experience requirement in the future (for example, by accepting more extended criteria organs for its patients). We accept the plan of correction and approve the center.

Example 3: A small kidney center that is currently approved under the ESRD CfCs applies for approval under the new CoPs. The kidney center meets the data submission requirement. The center performed 2 of the 10 transplants in the preceding 12 months and its outcomes are slightly below what is required under the CoPs. Although the center failed to meet both the clinical experience and the outcome requirements, we will review the transplant center's compliance with the other conditions of participation before making a decision on its request for approval. However, it is unlikely that we will grant approval under such conditions.

Example 4: A lung center located in a large city in the northeastern United States applies for Medicare approval under the requirements in the final rule. The lung center is currently Medicare approved. The center meets the data submission and clinical experience requirements. However, the center's 1-year observed patient and 1-year observed graft survival has been considerably below its expected 1-year expected patient and 1-year expected graft survival for the entire 2.5 year cohort. The center's outcomes show no sign of trending upward. We deny the center's request for approval. The center is free to re-apply at any time.

In summary, the flexibility of the initial approval process in this final rule will permit us to survey and possibly approve transplant centers that fail to meet the data submission, clinical experience, or outcome requirements when there are mitigating circumstances or when a transplant center's reported outcomes do not reflect the general high quality of its transplantation services. Based on the comments we received, § 488.61(a)(3) has been revised to read ''If CMS determines that a transplant center has not met the data submission, clinical experience, and outcome requirements, CMS may deny the request for approval or may review the center's compliance with the conditions of participation at § 482.72 through § 482.76 and § 482.90 through § 482.104, using the procedures described at 42 CFR part 488, subpart A, to determine whether the center's request will be approved. CMS will notify the transplant center in writing whether it is approved and, if approved, the effective date of its approval.''

Initial Approval Procedures For Centers With Current Medicare Approval

Comment: Commenters objected to the proposed requirement that all transplant centers with current Medicare approval must apply for initial approval under the CoPs.

Response: We do not believe it would be in the best interests of Medicare beneficiaries awaiting organ transplants to automatically approve centers with current Medicare approval because these centers were approved under NCDs for heart, liver, lung, and intestine centers or the ESRD CfCs for kidney transplant centers, which are different in many aspects from the CoPs in this final rule. For example, there are no outcome requirements for kidney transplant centers in the ESRD CfCs. Further, we know that some extra-renal transplant centers that were approved based on NCD criteria no longer meet those criteria. Therefore, automatically approving centers with current Medicare approval has the potential to permit a number of poor or marginal performers to continue to participate in Medicare. Based on these considerations, prior to approving currently approved transplant centers under our new requirements, we must first verify that they meet the CoPs in this final rule. The requirement for all currently-approved transplant centers to re-apply for initial approval under these new standards is consistent with our goals to increase transparency in the approval process and strengthen our oversight authority.

We expect all transplant centers, including kidney transplant centers, that are Medicare approved as of the effective date of this final rule that wish to continue to provide services to Medicare beneficiaries to be in compliance with the CoPs at §§ 482.72 through 482.104, as of the effective date of this final rule. Such transplant centers have 180 days from the effective date of this final rule to submit a request for Medicare approval under the CoPs at §§ 482.72 through 482.104, using the process described at § 488.61(b).

CMS will consider mitigating factors, including (but not limited to) the following in considering approval of a transplant center that does not meet the conditions of participation: the extent to which outcome measures are met or exceeded, availability of Medicare-approved transplant centers in the area, and extenuating circumstances (e.g., natural disaster) that may have a temporary effect on meeting the conditions of participation. In addition, the transplant center must submit to CMS and implement a plan of correction to meet the conditions of participation.

We will determine whether to approve the transplant center using the procedures described in paragraphs § 488.61(a)(2) through (a)(5). Until we make a determination whether to approve the transplant center's request for approval, the transplant center will continue to be approved under the ESRD CfCs (for kidney transplant centers) or the pertinent NCDs (for extra-renal transplant centers), as applicable. The transplant center will continue to be reimbursed for services provided to Medicare beneficiaries.

Once we approve a kidney transplant center under the CoPs, the ESRD CFCs will no longer apply to the transplant center as of the date of its approval. Once we approve an extra-renal transplant center under the conditions of participation, the NCDs will no longer apply to the transplant center as of the date of its approval. (See § 488.61(b).) Until we approve a currently approved transplant center under the CoPs in this final rule, the transplant center must continue to comply with the requirements in the NCDs or the ESRD CFCs, as applicable.

If a transplant center that is Medicare approved as of the effective date of this final rule does not submit a request to us for Medicare approval under the CoPs at §§ 482.72 through 482.104 within 180 days after the effective date of the final rule, or if the transplant center applies timely, but we do not approve the transplant center under the CoPs in this final rule, we will revoke the transplant center's approval under the CfCs for kidney transplant centers or the NCDs for extra-renal transplant centers, as applicable, and the transplant center will no longer be reimbursed for services provided to Medicare beneficiaries. CMS will notify the transplant center in writing of the effective date of its loss of Medicare approval.

Re-Approval Procedures

We asked the public and the five peer reviewers to comment on the following re-approval issues: (1) The feasibility and utility of the alternative approach to re-approve transplant centers based on random surveys; (2) methodology for selecting a random sample for surveys; (3) the necessity of surveying all centers every 3 years, regardless of their compliance with data submission and outcome measure requirements; and (4) the appropriateness of making re-approval survey decisions based on OPTN information (that is desk review, on-site audits and action(s) taken since last Medicare approval).

Following are the comments we received and our responses.

(1) The Feasibility and Utility of the Alternative Approach To Re-Approve Transplant Centers Based on Random Surveys

Comment: A peer reviewer agreed that a transplant center's compliance with data submission and outcome measure requirements by itself is not sufficient evidence for CMS to grant Medicare re-approval. However, two peer reviewers did not agree with using random surveys to identify transplant programs with deficiencies and stated that random surveys would miss many programs whose performance may warrant a survey. One peer reviewer supported using random surveys to re-approve transplant centers and believed it to be a systematic approach to assess transplant centers. One peer reviewer stated that Medicare's re-approval process should rely on the OPTN's monitoring and oversight process for transplant centers.

Many public commenters also agreed with our concern that a center's compliance with data submission and outcome requirements may not necessarily indicate a center is also in compliance with the process requirements. These commenters supported targeted or random surveys to determine re-approval decisions. However, one commenter said that random surveys for re-approval are unnecessary if a center has demonstrated consistent compliance with the requirements.

Response: We recognize that transplant center performance varies greatly and random surveys of centers may not be able to identify all poor performers. After carefully evaluating all the comments and taking into consideration the results of our recent survey of transplant centers, we believe finite resources are best used to survey the poorest performers and centers with significant deficiencies. Therefore, we will not perform random surveys as part of the re-approval process for transplant centers. Instead, we will review centers that do not meet the data submission, clinical experience, and outcome requirements for compliance with the CoPs before making our re-approval decision. The review may include an on-site visit. Under the final rule at § 488.61(c)(2), if we determine that a transplant center has not met the data submission, clinical experience, or outcome requirements at § 482.82, the transplant center will be reviewed for compliance with the conditions of participation at § 482.72 through § 482.76 and § 482.90 through § 482.104, using the procedures described at 42 CFR part 488, subpart A. Under the final rule at § 488.61(c)(3), if we determine that a transplant center has met the data submission, clinical experience, and outcome requirements at § 482.82, we may choose to review the transplant center for compliance with the conditions of participation at § 482.72 through § 482.76 and § 482.90 through § 482.104, using the procedures described at 42 CFR part 488, subpart A.

CMS will consider mitigating factors, including (but not limited to) the following in considering approval of a transplant center that does not meet the conditions of participation: The extent to which outcome measures are met or exceeded, availability of Medicare-approved transplant centers in the area, and extenuating circumstances (e.g., natural disaster) that may have a temporary effect on meeting the conditions of participation. In addition, the transplant center must submit to CMS and implement a plan of correction to meet the conditions of participation.

During the Medicare approval cycle, a transplant center will be reviewed at some point to ensure it is in compliance with the CoPs. The existing complaint investigation process and the use of relevant data, including the OPTN data, are good tools to identify centers with deficiencies.

As stated earlier, the OPTN and CMS oversight have a different focus, and they compliment each other. Therefore, we disagree with the commenter that OPTN oversight can substitute for CMS oversight. Further, we do not have the statutory authority to delegate regulatory authority to the OPTN to regulate transplant centers. No changes have been made in this final rule based on this comment.

(2) Methodology To Select a Random Sample for Surveys

Comment: Most peer reviewers had no comments on this issue. One peer reviewer suggested that 5–10% of small and large organ-specific centers should be selected for random surveys.

Response: We thank the peer reviewer for his suggestions. However, as stated in our responses earlier, we are not using random surveys to make re-approval decisions in this final rule. No changes have been made based on this comment.

(3) Whether Centers Should Be Surveyed Once Every 3 Years, Regardless of Their Compliance With Data Submission and Outcome Measure Requirements

Comment: A few commenters recommended surveying only centers that fail to comply with data submission and outcome measure requirements every 3 years. A commenter stated that all centers should be surveyed for compliance with the process requirements every 3 years, regardless of whether they are in compliance with data and outcome requirements. The commenter suggested allowing a plan of correction if a center is out of compliance with one or more conditions for coverage. Another commenter recommended that re-approval surveys be conducted only when a center has become an OPTN ''member not in good standing'' and only after exhaustion of all OPTN appeals processes and remedies. A commenter recommended that transplant centers be subject to only one survey every 3 years by either the OPTN or CMS but not both because surveys are burdensome, bureaucratic, and costly.

Two peer reviewers supported routine periodic survey of transplant centers for the purposes of: (1) Validating the timeliness and accuracy of data submission, (2) enhancing transplant centers' self-assessment process, and (3) sharing best practices to improve performance. A peer reviewer recommended surveying only centers that fail to comply with data submission and outcome measure requirements every 3 years. One peer reviewer stated that routine surveys are burdensome for centers that are performing well.

Response: We agree with the commenters and peer reviewers that transplant centers' data submission and outcome performance should be reviewed regularly to ensure they are in compliance with all of our requirements, even if they are consistently in compliance with data submission and clinical experience requirements. Nonetheless, we are also mindful of the potential burden on centers that are in compliance with the CoPs. Therefore, we will minimize the burden for transplant centers by conducting targeted re-approval surveys. For example, a center that barely meets the outcome requirements may be surveyed every 3 years, while a center that consistently has superior outcomes may be surveyed less often.

As stated previously, transplant centers will be subject to the same remediation process, including plans of correction, used for nearly all other Medicare providers and suppliers.

Also, we disagree with the commenter's suggestion to use the OPTN membership status of ''not in good standing'' as a trigger for surveys because the OPTN may designate a member as ''not in good standing'' for reasons that have nothing to do with the center's compliance with CMS's regulatory requirements (for example, OPTN organ allocation policies). If a transplant center were to become an OPTN ''member not in good standing,'' we most likely would treat the member's status with the OPTN as a complaint and conduct a survey of the center to determine its compliance with our regulatory requirements. If a Medicare provider is substantially out of compliance with our conditions of participation, we must take independent action promptly to oversee the provider's development and implementation of a plan of correction. We must base our decision whether to review or survey a center on issues that directly relate to the requirements in this final rule. Therefore, no changes have been made based on this comment.

Comment: Some commenters supported the re-approval procedures for Medicare-approved transplant centers and the 3-year re-approval cycle. However, some commenters suggested extending the approval cycle to 5 or 6 years.

Response: We agree with the commenters that centers should be monitored and re-approved every 3 years. Ongoing evaluation is critical to ensure that after Medicare approval, a center continues to meet Medicare requirements. Frequent, active oversight of transplants centers helps to ensure that Medicare beneficiaries continue to receive high quality transplantation services. We disagree that 5 or 6 years is an appropriate time period for re-

approval. Given rapid changes in the field of transplantation, a center's performance may change radically in 5 or 6 years from its initial Medicare approval.

Comment: A peer reviewer requested clarification on whether CMS will rely on the OPTN's Membership and Professional Standards Committee's (MPSC) extensive method to flag centers for further review or develop a similar method for this scrutiny.

Response: We plan to convene a technical expert panel to develop a similar methodology for targeting transplant centers for survey. However, we expect to minimize burden for transplant centers by conducting targeted re-approval surveys.

Comment: A peer reviewer favored a periodic ''self-study'' report by all programs regarding the state of their compliance with process requirements. A robust self-study process could potentially eliminate the need for, or reduce the frequency of, on-site surveys.

Response: We welcome the idea of transplant centers performing periodic ''self-study'' to assess their compliance with the process requirements. We urge transplant centers to consider incorporating a robust self-study process to enhance their preparedness for surveys. No changes have been made based on this comment.

(4) Use of OPTN Information To Identify Centers That Need To Be Surveyed

Comment: Many commenters agreed that it would be appropriate to make survey decisions based on OPTN information since it is widely accepted by U.S. health care payers. Nonetheless, a peer reviewer cautioned that routine use of OPTN information may alter the generally collegial responses that the OPTN receives from transplant programs. Transplant centers may become less open, less responsive, and more guarded. The peer reviewer said that this possibility should be carefully considered if the OPTN information-based survey approach is taken. The peer reviewer also recommended that we clearly define the thresholds for passing OPTN information to CMS.

Another peer reviewer was concerned that the sharing of OPTN data with CMS jeopardizes the confidentiality of transplant centers' data submissions to the OPTN under applicable laws and regulations protecting peer review processes employed by the OPTN committees. The reviewer recommended adding language to note that nothing in the final rule changes existing OPTN rules and policies with respect to confidentiality of data obtained from centers, as part of its oversight and compliance obligations.

Response: We agree that the use of OPTN information for survey decisions is appropriate since it is transparent, acceptable to the transplant community, and is publicly available. We will use relevant information such as OPTN data to prioritize survey decisions.

We do not believe the sharing of OPTN data with us jeopardizes the confidentiality of transplant centers' data under applicable laws and regulations because the OPTN final rule at 42 CFR part 121, states in § 121.11(b)(1)(iii) that the OPTN and the SRTR, as appropriate, shall provide to the Secretary any data that the Secretary requests. Because of the language in part 121, we do not see a need to add clarifying language with respect to confidentiality of data obtained from centers. We expect the OPTN/MPSC to continue its review process to flag centers for further review and we expect that centers will continue to maintain their collegial relationships with the OPTN.

Comment: A public commenter asked whether CMS or some other agency or organization will monitor transplant center's compliance with the outcome requirements. One commenter recommended that CMS consult with the OPTN.

A peer reviewer stated that we need to delineate the methodology we will use to survey transplant centers, identify the designated organization that will perform the surveys, and provide assurance that the organization has the experience and expertise to perform transplant center surveys.

Response: Although we have not yet determined which entity will monitor extra-renal transplant centers, we will inform them as soon as possible. Kidney transplant centers will not be monitored by any of the national accrediting bodies. Pursuant to sections 1865(b)(1) and 1881(b) of the Act, kidney transplant centers cannot be deemed by a national accreditation body to meet the Medicare conditions of participation. If a national accrediting organization applies for deeming authority for any of the extra-renal transplant centers, we will assess its expertise and review its application. If an accrediting organization is approved for deeming authority the transplant centers will be routinely reviewed (which could include surveys) by the accrediting organization. We will continue to have oversight responsibility for complaint surveys and validation surveys and will work closely with the accrediting organization on an ongoing basis. Most transplant centers are located in accredited hospitals and surveys of the transplant center may be combined with the routine survey of the hospital which may allow for a more efficient review since some of the transplant center documentation and records will be combined with the hospital records. We will include information about how transplant center surveys will be performed in the Interpretive Guidelines that we will develop following publication of the final rule. Under this final rule, we will monitor transplant center compliance with the clinical experience and outcome requirements. We will continue to work with the OPTN through HRSA on transplant center issues.

Accreditation, Corrective Actions, Appeal Process and Loss of Medicare Approval

We requested comments on whether transplant centers should be regarded as providers or as suppliers for the purpose of appealing adverse approval and re-approval decisions.

Comment: A commenter suggested that transplant centers should be identified as a provider in the regulations for accreditation and appeals purposes. One commenter suggested that the part 498 appeals process is an appropriate mechanism for transplant center appeals. Another commenter requested that we state clearly that the denial of initial approval and re-approval is a determination that triggers appeal rights under part 498.

Response: We agree with the commenter that transplant centers should have provider status for accreditation and appeals purposes because transplant centers are located within hospitals, which are considered providers under the Medicare program. Therefore, we have added transplant centers to the list of providers in 42 CFR 498.2 that have the right to appeal decisions that affect their participation in the Medicare program. Additionally, we have added transplant centers to the list of providers and suppliers in 42 CFR 488.6 that can receive deemed status through an accrediting organization. Transplant centers that apply for and are denied Medicare approval, as well as Medicare-approved transplant centers that are terminated from the Medicare program may appeal these decisions under part 498.

Comment: A few commenters recommended that a center should be allowed to continue Medicare participation pending exhaustion of any appeals, provided that its treatment of Medicare beneficiaries does not jeopardize their health and safety.

Response: In most cases, Medicare providers and suppliers are permitted to continue to participate in Medicare while an appeal is pending, unless the deficiency is such that the health and safety of patients is in immediate jeopardy.

Comment: Many commenters asked us to clarify whether transplant centers that do not meet the data and outcome requirements in the initial approval and re-approval process will have an opportunity for corrective action. A commenter suggested that we should provide a process of remediation and corrective actions for centers that fail to comply with the data submission and outcome requirements that is like the process for hospitals that face termination from the Medicare program. A commenter recommended 180 days for centers to submit acceptable plans of correction and correct deficiencies through the use of an acceptable QAPI program. Another commenter stated that we should consult with the OPTN before denying re-approval of Medicare-approved centers. A commenter suggested that we should review a center for potential termination of Medicare approval only when the Secretary has been notified of an OPTN decision to take adverse action against the center. A commenter recommended that we adopt the OPTN remediation process for centers failing to meet outcome requirements.

Response: Once approved under the requirements of this final rule, transplant centers will be subject to the same remediation process used for nearly all other Medicare providers and suppliers. Under the process for re-approval, a transplant center found to be out of compliance with one or more CoPs, including the CoP for data submission, clinical experience, and outcome requirements, will have an opportunity to come back into compliance once it has submitted an acceptable plan of correction. Generally, the transplant center will be permitted to continue to provide services to Medicare beneficiaries while we monitor implementation of the plan of correction. We also will use this process if we find, during a complaint investigation, that a transplant center is out of compliance with one or more conditions of participation. We do not have a remediation or corrective action process for entities that apply for initial Medicare certification or approval under this final rule and fail to meet the requirements. However, a transplant center that is not approved may re-apply for initial approval at any time.

We will include additional details about the processes for initial approval and re-approval, plans of correction, and other matters related to survey and certification of transplant centers in Interpretive Guidelines for surveyors and manual instructions that will be published following the effective date of this final rule.

III. Provisions of the Final Rule

In the final rule, we are adopting the provisions as set forth in the February 4, 2005 proposed rule with the following revisions:

Amend § 482.70, ''Definitions,'' by—

- Revising the term ''adverse event.'' The proposed definition listed two examples of adverse events related to living donors: ''living donor death due to mismanagement of the donor'' and ''avoidable loss of a healthy living donor.'' We have replaced these two examples with ''serious medical complications or death caused by living donation'' to clarify that the death or serious medical complications due to living donation of any living donor should be investigated as an adverse event. The proposed definition also listed another example of an adverse event as ''transplantation of organs of mismatched blood types due to failure to validate the donor and recipient's vital information.'' We have revised this example to now read ''unintentional transplantation of organs of mismatched blood types'' in order to further clarify this term.
- Removing the term ''intestinal'' wherever it appears, when referring to such transplants and transplant centers, and adding in its place the term ''intestine.''

Amend § 482.72, ''Condition of participation: OPTN membership,'' by—

- Revising the beginning of the last sentence in the condition statement by changing it from ''No transplant hospital * * *'' to ''No hospital that provides transplantation services * * *''

Amend § 482.74, ''Condition of participation: Notification to CMS,'' by—

- Redesignating the proposed introductory text as paragraph (a) and proposed paragraphs (a) and (b) as paragraphs (a)(1) and (a)(2) respectively.
- Revising the newly redesignated paragraph (a) to read ''A transplant center must notify CMS immediately of any significant changes related to the center's transplant program or changes that could affect its compliance with the conditions of participation. Instances in which CMS should receive information for follow up, as appropriate, include, but are not limited to: * * *''
- Redesignating § 482.100(b) as § 482.74(a)(3) and revising newly designated paragraph (a)(3).
- Adding a new paragraph (a)(4) to clarify that a transplant center must notify CMS immediately of its inactivation.
- Adding a new paragraph (b) to specify the actions CMS will take to follow-up with a transplant center that notifies us of significant changes in their program.

Amend § 482.76, ''Condition of participation: Pediatric transplants,'' by—

- Removing the word ''wishes'' and adding in its place ''seeks Medicare approval'' in the condition statement to clarify that it is only those centers seeking Medicare approval to perform pediatric transplants that must submit a request for this specific purpose.
- Adding the phrase ''in a 12-month period'' after ''A center that performs 50 percent or more of its transplants,'' at proposed § 482.76(b) to clarify that a center that performs predominately adult transplants must be approved to perform adult transplants in order to be approved to perform pediatric transplants.
- Adding the phrase ''in a 12-month period'' after ''A center that performs 50 percent or more of its transplants'' at proposed § 482.76(c) to clarify that a center that performs predominately pediatric transplants must be approved to perform pediatric transplants in order to be approved to perform adult transplants.
- Revising proposed § 482.76(c)(3) to read ''A center that performs 50 percent or more of its transplants on pediatric patients in a 12-month period is not required to meet the clinical experience requirements prior to its request for approval as a pediatric transplant center.
- Adding the citation of ''Omnibus Budget and Reconciliation Act (OBRA) 1987 criteria in section 4009(b) (Pub. L. 100–203)'' at paragraph (d) to clarify that the alternate criteria for Medicare approval of heart transplant centers providing transplantation services to pediatric heart patients are mandated by statute, and in paragraph (d)(1) changing the word ''center'' to ''hospital'' to conform with the language in OBRA 1987.

Amend § 482.80, ''Condition of participation: Data submission and outcome requirements for initial approval of transplant centers,'' by—

- Adding the phrase ''clinical experience'' to the CoP section heading and to the condition statement to clarify that there is a clinical experience requirement, and so that the heading now reads ''Data submission, clinical experience, and outcome requirements for initial approval of transplant

centers.'' (The appropriate revisions regarding the clinical experience requirements for approval and re-approval, including the special procedures for approval and re-approval described at § 488.61, have been made throughout the final rule.)

• Revising the condition statement. Throughout the proposed rule the terms ''outcome measure'' and ''outcome measure standards'' are used. We have replaced both terms with ''outcome requirements'' here and throughout the final rule in order to clarify, through the use of a uniform term throughout, that these are requirements and not measures or standards. We have done this, along with our removal of the reference to waivers in the proposed rule, in order to further clarify that centers not meeting the data submission, clinical experience, and outcome requirements may be reviewed to augment CMS's approval decisions.

• Removing in paragraph (a) ''transplant recipient registration, and recipient follow-up'' and adding in its place the words ''transplant recipient registration and follow-up.'' In addition, adding at the end of paragraph (a) ''and living donor registration and follow-up'' to clarify that they are part of the required data submissions.

• Adding a new paragraph (b), Standard: Clinical Experience requirements. An organ-specific transplant center generally must perform 10 transplants over a 12-month period.

• Re-designating proposed § 482.80 paragraph (b) as paragraph (c) and revising the paragraph heading to now read ''(c) Standard: Outcome requirements.'' All references to this paragraph have been amended accordingly.

• Revising proposed § 482.80 paragraph (b)(1) (now (c)(1)) by removing the words '' as long as the center has 1-year post-transplant follow-up on at least 9 transplants of the appropriate organ type.''

• Revising proposed § 482.80 paragraph (b)(2) (now (c)(2)) by removing the words ''The 9'' and adding in its place the words ''The required number of'' so that the paragraph now reads: ''The required number of transplants must have been performed during the time frame reported in the most recent SRTR center-specific report.''

• Removing proposed § 482.80 paragraphs (b)(4), (b)(5), and (b)(6) to clarify that a center may not request CMS to review its 1-month patient and graft survival outcomes for all transplants performed in the previous 1-year period in lieu of 1-year patient and graft survival outcomes if certain conditions are met. We are not finalizing the proposed review of 1-month post-transplant data of new centers seeking Medicare approval.

• Re-designating proposed § 482.80 paragraph (c) as paragraph (d) with the heading continuing to read ''Exceptions.'' All references to this paragraph have been amended accordingly.

• Revising newly re-designated paragraph (d)(1) to clarify that heart-lung transplant centers are not required to meet the clinical experience requirements or the outcome requirements for heart-lung transplants performed at the center.

• Revising newly re-designated paragraph (d)(2) to clarify that intestine transplant centers are not required to meet the outcome requirements for intestine, combined liver-intestine, or multivisceral transplants performed at the center.

• Revising newly re-designated paragraph (d)(3) to clarify that pancreas transplant centers are not required to meet the clinical experience requirements or the outcome requirements for pancreas and kidney-pancreas transplants performed at the center.

• Removing in newly re-designated paragraph (d)(4) the words ''perform a minimum number of pediatric transplants'' and adding in its place the words ''comply with the clinical experience requirements in paragraph (b)'' to clarify that a center requesting initial Medicare approval to perform pediatric transplants does not have to comply with the clinical experience requirements prior to its request for approval as a pediatric transplant center.

• Adding paragraph (d)(5) to state that ''a kidney transplant center that is not Medicare-approved on the effective date of this final rule is required to perform at least 3 transplants over a 12-month period prior to its request for initial approval.''

Amend § 482.82 ''Condition of participation: Data submission and outcome requirements for re-approval of transplant centers'' by—

• Adding the phrase ''clinical experience'' to the CoP section heading and to the condition statement to clarify that there is a clinical experience requirement, and so that the heading now reads ''Data submission, clinical experience, and outcome requirements for re-approval of transplant centers.''

• In paragraph (a), revising ''transplant recipient registration, and recipient follow-up'' to read ''transplant recipient registration and follow-up.'' In addition, adding the words ''and living donor registration and follow-up'' at the end of paragraph (a) to clarify that they are part of the required data submission.

• Adding a new paragraph (b), Standard: Clinical experience requirements. An organ-specific transplant center must generally perform an average of 10 transplants per year during the re-approval period.

• Re-designating proposed paragraph (b) as paragraph (c) and revising the paragraph heading to now read ''(c) Standard: Outcome requirements.'' All references to this paragraph have been amended accordingly.

• Revising proposed paragraph (b)(1) (now (c)(1)) by removing the phrase ''as long as the center has 1-year post-transplant follow-up on at least 9 transplants of the appropriate organ type.''

• Revising proposed § 482.82 paragraph (b)(2) (now (c)(2)) by removing the words ''The 9'' and adding in its place the words ''The required number of'' so that it now reads: ''The required number of transplants must have been performed during the time frame reported in the most recent SRTR center-specific report.''

• Re-designating proposed § 482.82 paragraph (c) as paragraph (d) with the paragraph heading continuing to read ''Exceptions.'' All references to this paragraph have been amended accordingly.

• Revising newly re-designated paragraph (d)(1) to clarify that heart-lung transplant centers are not required to meet the clinical experience requirements or the outcome requirements for heart-lung transplants performed at the center.

• Revising newly re-designated paragraph (d)(2) to clarify that intestine transplant centers are not required to meet the outcome requirements for intestine, combined liver-intestine, or multivisceral transplants performed at the center.

• Revising newly re-designated paragraph (d)(3) to clarify that pancreas transplant centers are not required to meet the clinical experience requirements or the outcome requirements for pancreas and kidney-pancreas transplants performed at the center.

• Revising newly re-designated paragraph (d)(4) by removing the phrase ''perform a minimum number of pediatric transplants'' and adding in its place the words ''comply with the clinical experience requirements in paragraph (b)'' in order to clarify that a center does not have to comply with the clinical experience requirements to be re-approved.

Amend § 482.90 ''Condition of participation: Patient and living donor selection'' by—

• Removing the word ''waitlist'' and adding in its place the words ''waiting list'' in the condition statement and throughout the requirements where applicable.

• Removing proposed paragraph (a)(1) and re-designating paragraphs (a)(2), (a)(3), and (a)(4) as paragraphs (a)(1), (a)(2), and (a)(3).

• Revising newly re-designated paragraph (a)(1) by adding the words, ''if possible'' at the end of the sentence to allow transplant centers the discretion to give psychosocial evaluation to prospective transplant candidates.

• Adding the words ''transplant patient'' to paragraph (a)(4) which reads ''A transplant center must provide a copy of its patient selection criteria to a transplant patient or dialysis facility, if requested by such transplant patient or facility.''

• Removing the words ''transplant candidate's'' in proposed paragraph (b)(2) so that the transplant center is only required to document the living donor's suitability for donation in the living donor's medical record.

Revise § 482.92 ''Condition of participation: Organ recovery and receipt'' by—

• Revising the first line of the condition statement to read ''Transplant centers must have written protocols for validation of donor-recipient blood type and other vital data for the deceased organ recovery, organ receipt, and living donor organ transplantation process.''

• Adding the phrase ''When the identity of an intended transplant recipient is known and the transplant center sends a team to recover organ(s),'' at the beginning of paragraph (a) to clarify that if the intended recipient for the organ being recovered is known, the transplant center's recovery team must review and compare the donor data with the recipient blood type and other vital data before organ recovery takes place.

• Adding the phrase ''a licensed health care professional'' to paragraph (b) to clarify that this individual must be present for the verification of donor's blood type and vital data when an organ arrives at the transplant center.

Amend § 482.94 ''Condition of participation: Patient and living donor management'' by—

• Removing the word ''pre-transplant'' in the condition statement and in paragraph (a)(1) to clarify that a transplant center is not required to provide the care of a multidisciplinary patient care team coordinated by a physician in the pre-transplant phase of transplantation.

• Removing the words ''on an ongoing basis'' in paragraph (b)(1) and adding them to paragraph (b) introductory text to clarify that transplant centers must keep their waiting lists up to date on an ongoing basis.

• Adding the phrase ''(and in the case of a kidney patient, the patient's usual dialysis facility)'' in paragraph (c)(1) to clarify that the dialysis facility of the kidney transplant patients must also be notified of the patient's transplant status''.

• Adding the phrase ''(and in the case of a kidney patient, the patient's usual dialysis facility)'' in paragraph (c)(2) to clarify that the dialysis facility of the kidney transplant patients must also be notified of the kidney patient's removal from the waiting list for any reason other than death or transplantation no later than 10 days after the date the patient was removed from the waiting list.

• Removing the requirement in proposed (c)(2)(i)that once a patient is placed on a center's waiting list, the center must document in the patient's record that the patient is notified of his or her placement status at least once a year, even if there is no change in the patient's placement status. We are not finalizing this proposed requirement.

• Re-designating the proposed paragraph (c)(2)(ii) as paragraph (c)(2).

• Removing proposed paragraph (c)(3).

• Revising proposed paragraph (c)(4)(i) to replace the word ''pre-transplant'' with ''transplant.''

• Re-designating proposed paragraph (c)(4) as paragraph (c)(3).

• Revising proposed paragraph (d) to now define a qualified social worker as ''an individual who meets licensing requirements in the State in which he or she practices; and (1) Has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education; or (2) Is working as a social worker in a transplant center as of the effective date of this final rule and has served for at least 2 years as a social worker, 1 year of which was in a transplantation program, and has established a consultative relationship with a social worker who is qualified under § 482.94(d)(1) of this paragraph.

• Revising proposed paragraph (e) by removing paragraphs (e)(1) and (e)(2), and now defining a qualified dietitian as an individual who meets practice requirements in the State in which he/she practices and who is a registered dietitian with the Commission on Dietetic Registration.

Amend § 482.96 ''Condition of participation: Quality assessment and performance improvement (QAPI)'' by—

• Adding in paragraph (a) the word ''requirements'' after the words ''OPTN waitlist (now waiting list)'' in order to further clarify this example of a QAPI program activity.

• Adding in paragraph (a) the words ''patient education'' to clarify that this is one of the included QAPI activities and outcomes.

Amend § 482.98 ''Condition of participation: Human resources'' by—

• Revising proposed paragraph (a)(1) to read: ''Coordinating with the hospital in which the transplant center is located to ensure adequate training of nursing staff and clinical transplant coordinators in the care of transplant patients and living donors' to further clarify the responsibilities of the Director of a transplant center.

• Revising paragraph (a)(3), to clarify that the director of the transplant center is responsible for ensuring that surgery is performed ''by, or under the direct supervision of, a qualified transplant surgeon.''

• Adding the phrase ''and who are immediately available to provide transplantation services when an organ is offered for transplantation'' at the end of the sentence at paragraph (b) to clarify that a transplant surgeon and physician must be immediately available to perform a transplant when an organ is offered.

• Removing in paragraph (c), the portion of the definition of a qualified clinical transplant coordinator, which requires an individual to be certified by the American Board of Transplant Coordinators, and adding in its place an expanded one that states ''The clinical transplant coordinator must be a registered nurse or other licensed clinician who has experience and knowledge of transplantation and living donation issues. The clinical transplant coordinator's responsibilities must include, but are not limited to, the following: (1) Ensuring the coordination of the clinical aspects of transplant patient and living donor care; and (2) Acting as a liaison between a kidney transplant center and dialysis facilities, as applicable.''

• Adding a new standard at paragraph (d) titled ''Independent living donor advocate or living donor advocate team.'' This new requirement states ''The transplant center that performs living donor transplantation must identify either an independent living donor advocate or an independent living donor advocate team to ensure

protection of the rights of living donors and prospective living donors.'' As noted below, this new standard also has three new provisions contained within it.

• Requiring under the new paragraph (d)(1) that the living donor advocate or living donor advocate team must not be involved in transplantation activities on a routine basis.

• Requiring under the new paragraph (d)(2) that these independent advocates or advocate teams must demonstrate: (i) Knowledge of living organ donation, transplantation, medical ethics, and informed consent; and (ii) understanding of the potential impact of family and other external pressures on the prospective living donor's decision whether to donate and the ability to discuss these issues with the donor.

• Requiring under the new paragraph (d)(3) that the independent living donor advocate's or living donor advocate team's responsibilities include: (i) Representing and advising the donor; (ii) protecting and promoting the interests of the donor; and (iii) respecting the donor's decision and ensuring that the donor's decision is informed and free from coercion.

• Re-designating proposed § 482.98 paragraph (d) as paragraph (e) with heading continuing to read ''Standard: Transplant team.'' All references to this paragraph have been amended accordingly.

• Re-designating proposed § 482.98 paragraph (e) as paragraph (f) with heading continuing to read ''Standard: Resource commitment.'' All references to this paragraph have been amended accordingly.

• Adding the words ''patient education'' in newly re-designated paragraph (f) to clarify that this is one of the areas of expertise that a transplant center is required to have available under its resources.

Amend § 482.100 ''Condition of Participation: Organ procurement'' by—

• Removing the paragraph designation ''(a)'' and combining the text with the condition statement.

• Re-designating proposed paragraph (b) as § 482.74(a)(3) and revising newly designated § 482.74(a)(3) to read ''Termination of an agreement between the hospital in which the transplant center is located and an OPO for the recovery and receipt of organs;''.

Amend § 482.102 ''Condition of participation: Patient and living donor rights'' by—

• Adding the words ''Patient rights'' to the condition statement to clarify that § 482.13 is the Patients rights CoP.

• Revising proposed § 482.102 paragraph (a) to read ''Transplant centers must implement written transplant patient informed consent policies that inform each patient of: * * *''

• Amending paragraph (a)(5) to specify that information provided to patients includes (but is not limited to) information from the most recent SRTR center-specific report, including (but not limited to) the transplant center's observed and expected 1-year patient and graft survival, national 1-year patient and graft survival, and notification about all Medicare outcome requirements not being met by the transplant center.

• Removing the text of proposed paragraph (a)(6);

• Re-designating the proposed (a)(7) as (a)(6).

• Re-designating the proposed (a)(8) as (a)(7).

• Adding a new paragraph (a)(8) to read ''The fact that if his or her transplant is not provided in a Medicare-approved transplant center, it could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid for under Medicare Part B.''

• Revising proposed § 482.102 paragraph (b) to read ''Transplant centers must implement written living donor informed consent policies that inform * * * .''

• Adding paragraph (b)(9) to read ''The fact that if a transplant is not provided in a Medicare-approved transplant center, it could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid under Medicare Part B.''

• Deleting the phrase ''that meets the hospital's credentialing policies'' from proposed § 482.102 paragraph (c)(1)(ii) in order to clarify this provision.

• Revising proposed § 482.102 paragraph (c)(2)(ii) to read: ''Inform Medicare beneficiaries on the center's waiting list that Medicare will no longer pay for transplants performed at the center after the effective date of the center's termination of approval.''

• Adding a new provision at § 482.102(c)(3) that reads ''As soon as possible prior to a transplant center's voluntary inactivation, the center must inform patients on the center's waiting list and, as directed by the Secretary, provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list.''

Amend § 482.104 ''Condition of participation: Additional requirements for kidney transplant centers'' by—

• Revising proposed § 482.104 paragraph (a) by adding a new line that reads ''A kidney transplant center must have written policies and procedures for ongoing communications with dialysis patients' local dialysis facilities.''

• Removing the requirement at proposed § 482.104 paragraph (b) that kidney dialysis centers or units in kidney transplant centers providing dialysis services to inpatients directly or under arrangement must meet the Conditions of Coverage of Suppliers of ESRD Services contained in part 405 subpart U of this chapter. We are not finalizing this proposed requirement in the final rule.

Amend § 488.6 ''Other national accreditation programs for hospitals'' by—

• Revising paragraph (a), first sentence, by inserting the words ''transplant centers except for kidney transplant centers;'' after the words ''psychiatric hospitals;''.

Amend § 488.61 ''Special procedures for approval and re-approval of organ transplant centers'' by—

• Revising the heading to paragraph (a) to read ''Initial approval procedures for transplant centers that are not Medicare-approved as of June 28, 2007.''

• Revising paragraph (a) to clarify that a transplant center, including kidney transplant centers, may submit a request to CMS for Medicare approval at any time.

• Revising proposed § 488.61 paragraph (a)(2) to include provisions from proposed paragraph (a)(3) to read ''To determine compliance with the clinical experience and outcome requirements at § 482.80(b) and (c), CMS will review the data contained in the most recent OPTN Data Report and 1-year patient and graft survival data contained in the most recent Scientific Registry of Transplant Recipient (SRTR) center-specific report.''

• Deleting proposed paragraph (a)(3) and redesignating proposed paragraph (a)(4) as (a)(3). We revised proposed paragraph (a)(4), now (a)(3) to read: If CMS determines that a transplant center has not met the data submission, clinical experience, or outcome requirements, CMS may deny the request for approval or may review the center's compliance with the conditions of participation at § 482.72 through § 482.76 and § 482.90 through § 482.104 of this chapter, using the procedures described at 42 CFR part 488, subpart A, to determine whether the center's request will be approved. CMS will notify the transplant center in writing whether it is approved and, if approved, of the effective date of its approval.

• Adding a new paragraph (a)(4) to describe mitigating factors CMS will consider in determining initial approval

or re-approval of a transplant center that does not meet the data submission, clinical experience, outcome requirements and other conditions of participation.

• Revising paragraph (a)(5) to outline the initial Medicare approval review process and approval period, and to specify how transplant centers will be notified of approval.

• Deleting proposed paragraph (a)(6) and including its content in proposed paragraph (a)(4) (now (a)(3)).

• Adding a new paragraph (a)(6) to state that a kidney center may submit a request for initial approval after performing at lease 3 transplants over a 12-month period.

• Revising proposed paragraph (a)(7) for clarity.

All references to these paragraphs have been amended accordingly.

• Redesignating proposed paragraph (b) as paragraph (c).

• Adding a new paragraph (b) to clarify that all transplant centers, including kidney transplant centers, approved as of the effective date of this final rule that want to continue to be Medicare approved must submit a request to CMS for Medicare approval under the conditions of participation by December 26, 2007, using the process described in paragraph (a)(1) of the section. CMS will determine whether to approve a transplant center using the procedures described in paragraphs (a)(2) through (a)(5) of the section.

• Revising proposed paragraph (b) (now (c)), for clarity.

• Revising proposed § 488.61 paragraph (b)(1)(ii) (now (c)(1)(ii)) to read ''To determine compliance with the clinical experience and outcome requirements at § 482.82(b) and (c), CMS will review the data contained in the most recent OPTN Data Report and 1-year patient and graft survival data contained in the most recent Scientific Registry of Transplant Recipient (SRTR) center-specific report.''

• Revising proposed 488.61 paragraph (b)(4) (now (c)(1)) to read ''Prior to the end of the 3-year approval period, CMS will review the transplant center's data in making re-approval determinations.''

• Adding a new paragraph (c)(4) to describe mitigating factors CMS will consider in determining re-approval of a transplant center that does not meet the data submission, clinical experience, outcome requirements and other conditions of participation.

• Revising proposed § 488.61 paragraph (b)(4) (now (c)(5)) to read: ''CMS will notify the transplant center in writing if its approval is being revoked and of the effective date of the revocation.''

• Adding the phrase ''including kidney transplant centers'' to paragraph (c) to clarify that all transplant centers must be in compliance with all the CoPs for transplant center at § 482.72 through § 482.104, except for § 482.80 (Initial approval requirements) throughout the 3 year approval period.

• Adding a new transplant center inactivity requirement at paragraph (e) to state that a transplant center may inactivate its program for a period not to exceed 12 months during the 3-year approval cycle. A transplant center must notify CMS upon its voluntary inactivation as required by § 482.74(a)(4).

IV. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comments on the following issues:

• The need for the information collection and its usefulness in carrying out the proper functions of our agency.

• The accuracy of our estimate of the information collection burden.

• The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comments on each of these issues for the sections of this document that contain information collection requirements (ICRs).

General Comments

Comment: Some commenters said they were concerned that CMS generally underestimated the total burden hours and/or total estimated costs that this regulation would impose on transplant centers. Other commenters felt that some of the data used in the proposed rule were inaccurate.

Response: After further analysis of the tasks needed for the paperwork requirements in this final rule and review of more recent financial data, we agree with the commenters that for certain requirements, we underestimated the total burden hours (and in the economic impact analysis, the total estimated costs) associated with the paperwork requirements in the proposed rule. Therefore, we have increased our estimate of total burden hours and/or total costs for some of the conditions of participation. These changes are discussed below for each relevant condition of participation.

Comment: Some commenters said that many of the requirements in the proposed rule would be unnecessary because some of the proposed requirements are similar or identical to either current OPTN or JCAHO requirements.

Response: The commenters are correct; however, we disagree that these requirements are unnecessary. For these requirements to be enforceable by us through our oversight and survey and certification process, they must be promulgated as regulations.

Also, some commenters stated that the regulation would increase post-transplant health care costs. However, this final rule regulates only inpatient transplant services and will not increase the cost of providing post-transplant care once patients are discharged from the hospital.

Section 482.74 Condition of Participation: Notification to CMS

Section 482.74 requires a transplant center to notify us immediately of any significant changes related to the center's transplant program or changes that could affect its compliance with the CoPs. The instances in which a transplant center must notify us include, but are not limited to: any change in key staff members of the transplant team; a decrease in the number of the center's transplants or survival rates that could result in the center being out of compliance with § 482.82, Condition of participation: Data submission, clinical experience, and outcome requirements for re-approval of transplant centers; termination of an agreement between the hospital in which the transplant center is located and an OPO for the recovery and receipt of organs; and inactivation of the transplant center.

In the proposed rule, we estimated that the burden associated with this section would be the time required to notify us of significant changes. We estimated that there would be three occasions annually per center requiring notification. For each occasion, we estimated that it would take 5 minutes to notify us. Therefore, we estimated that it would take no more than 15 minutes annually for each center to notify us of any significant changes. We said that since there were approximately 900 transplant centers, we estimated that the total burden hours for

complying with this section would be a total of 225 hours. The estimate of 900 transplant centers included non-Medicare approved transplant centers. However, our analysis will only concern Medicare-approved centers.

Comment: One commenter said that we significantly underestimated the burden required for transplant centers to comply with this requirement. The commenter noted that notifying us of these changes required the involvement of the program's medical director, an administrator, and appropriate clerical/support staff. The commenter opined that large centers would have a significant number of changes per year, perhaps as many as 6–12, and that each change would require 15–30 minutes of time for each of the individuals involved or approximately one and one-half to two hours per change.

Response: We agree that we underestimated the burden of this requirement. We agree that reporting a significant change to us would require more than 5 minutes and would involve senior staff and management. After further analysis of the tasks involved in complying with this section and the personnel that generally would be involved.

TOTAL ANNUAL BURDEN HOURS AND TOTAL ANNUAL COST ESTIMATE FOR SUBMITTING SIGNIFICANT CHANGES TO CMS

Position	Hourly wage	Hours required per report	Total cost estimate for each report	Total annual burden hours per center (for 3 reports)	Total annual cost estimate per center (for 3 reports per year per center)
Medical Director	$116.60	.50	$58.30	1.5	$174.90
Senior Administrator	92.31	.50	46.16	1.5	138.46
Transplant Coordinator	43.87	.75	32.90	2.25	98.71
Secretary	21.81	.25	5.45	.75	16.36
Totals	.....	2.00	142.81	6.0	428.43

All salary information is from the salary.com Web site at *http://hrsalarycenter.salary.com.*

Section 482.76 Condition of Participation: Pediatric Transplants

Section 482.76 states that a transplant center that seeks Medicare approval to provide transplantation services to pediatric patients must submit to CMS a request specifically for Medicare approval to perform pediatric transplants using the procedures at § 488.61, Special procedures for approval and re-approval of organ transplant centers. The center requesting Medicare approval to perform pediatric transplants must meet all the conditions of participation in §§ 482.72 through 482.74 and §§ 482.80 through 482.104, with respect to its pediatric patients.

The burden associated with this requirement would be the time required to prepare and submit the required information and data to us. Since pediatric centers must comply with the procedures at § 488.61, the burden for pediatric centers to request Medicare approval will be analyzed under that section.

In lieu of meeting all of the requirements in those sections noted above, § 482.76(d) provides that a heart transplant center that wishes to provide transplantation services to pediatric heart patients may be approved to perform pediatric heart transplant by meeting the OBRA 1987 criteria in section 4009(b) (Pub. L. 100–203) as follows:

(1) The center's pediatric transplant program must be operated jointly by the hospital and another facility that is Medicare-approved;

(2) The unified program shares the same transplant surgeons and quality improvement program (including oversight committee, patient protocol, and patient selection criteria); and

(3) The center must demonstrate to the satisfaction of the Secretary that it is able to provide specialized facilities, services, and personnel that are required by pediatric heart transplant patients.

The burden associated with this requirement is the time required for heart transplant centers that choose to use the alternative criteria under § 482.76(d) to prepare and submit the required information to us. We believe that it would require additional time to apply using the alternative criteria in this section. However, we also believe that the additional burden would be minimal.

In addition, we believe that fewer than 10 entities would choose to apply for Medicare approval using the alternative criteria in this section in any given year. There are currently seven Medicare-approved pediatric heart transplant centers. Even if we should receive requests for Medicare approval from the equivalent of 50 percent of the currently approved centers, we would receive only about 4 requests. Under 5 CFR 1320.3(c), a ''collection of information'' does not include requirements imposed on fewer than ten entities. Therefore, the requirements under § 482.76(d) are not subject to the PRA.

Section 482.80 Condition of Participation: Data Submission, Clinical Experience, and Outcome Measure Requirements for Initial Approval of Transplant Centers

Section 482.80 requires that, except as specified in paragraph (d) of that section and at 488.61, transplant centers must generally meet all data submission, clinical experience, and outcome requirements to be granted initial approval by us. Section 482.80(a) requires transplant centers to submit to the OPTN at least 95 percent of the required data on all transplants (deceased and living donors) no later than 90 days after the date established by the OPTN. The required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration and follow-up, and living donor registration and follow-up.

The burden associated with this requirement is the amount of time it would take the transplant center to submit the required data. In the proposed rule, we stated that we believed that these requirements reflected usual and customary business practice and would be followed even if there were no Medicare requirements. Thus, we said that the burden for these requirements would be exempt under 5 CFR 1320.3(b)(2).

Comment: A national organization that represents professionals in the transplant community commented that the data submission requirements

necessary for OPTN compliance have had a huge financial impact on transplant centers. The commenter noted that multiple forms are required for each patient, from the time of registration on the OPTN waiting list to several years post-transplant. They noted that the analysis did not account for the additional resources needed to complete and submit these forms.

Response: Although we appreciate that the data submission requirements necessitate significant resources from the transplant centers, we would point out that OPTN policies require transplant hospitals as a condition of membership to submit these required data to the OPTN. The final rule governing the operation of the OPTN (42 CFR 121.11) also imposes this requirement by Federal regulation. Further, existing Medicare regulations require that if a hospital performs transplants, it must be a member of the OPTN and provide organ-transplant-related data, as requested, to the OPTN, SRTR, and the OPOs. (See 42 CFR 482.45(b).) Therefore, complying with this section imposes little additional burden on the transplant centers and constitutes usual and customary business practice.

Under 5 CFR 1320.3(b)(2), if the activities that are needed to comply with an ICR constitute usual and customary business practices, those activities should be excluded from the burden analysis. Thus, these activities will not be included in the burden analysis for this final rule.

Section 482.82 Condition of Participation: Data Submission, Clinical Experience, and Outcome Measure Requirements for Re-Approval of Transplant Centers

Section 482.82 provides that, except as specified in paragraph (d) of this section and at 488.61, transplant centers must meet all the data submission, clinical experience, and outcome requirements to be re-approved. Section 482.82(a) requires that no later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of the required data submissions on all transplants (deceased and living donors) it has performed over the 3-year approval period. The required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration and follow up, and living donor registration and follow up.

The burden associated with this requirement is the time it would take the transplant center to submit the required data. As discussed above under § 482.80, we already require hospitals in which transplant centers are located to belong to the OPTN, and the OPTN requires that these hospitals submit data to the OPTN. (See § 482.45(b).)

Thus, complying with this section imposes little additional burden on the transplant centers and constitutes usual and customary business practice. Under 5 CFR 1320.3(b)(2), if the activities that are needed to comply with an ICR constitute usual and customary business practices, those activities should be excluded from the burden analysis. Therefore, these activities will not be included in this final rule's burden analysis.

Section 482.90 Condition of Participation: Patient and Living Donor Selection

Section 482.90 requires transplant centers to use written patient selection criteria in determining a patient's suitability for placement on the waiting list or a patient's suitability for transplant. If a center performs living donor transplants, the center must also use written donor selection criteria in determining the suitability of candidates for donation.

Section 482.90(a) states that before a transplant center places a transplant candidate on its waiting list, the candidate's medical record must contain documentation that the candidate's blood type has been determined. When a patient is placed on a center's waiting list or is selected to receive a transplant, the center must document in the patient's medical record the patient selection criteria that were used. Section 482.90(b) states that a transplant center also must document in the living donor's medical records the living donor's suitability for donation and that the living donor has given informed consent, as required under § 482.102(b).

Comment: Some commenters said that the patient selection criteria requirements would be burdensome. For example, one commenter said that it would take at least 30 minutes of staff time to document the patient selection criteria in the file of each patient or living donor.

Response: We disagree. Each center has the flexibility to determine the most expedient way to satisfy this requirement. Centers should be able to reduce the resources needed to document individual potential transplant recipient and living donor medical records significantly by using electronic formats, forms, or checklists. Therefore, complying with this requirement constitutes a minimal burden to the transplant centers.

Comment: One commenter said that we did not address the recordkeeping burden for this requirement.

Response: For the reasons discussed immediately below, we do not believe a burden analysis of this requirement should be included in this PRA analysis.

The burden associated with complying with this section is the time to develop the transplant recipient and living donor selection criteria and document each potential transplant recipient's and living donor's medical record. We expect that all transplant centers have policies regarding selection criteria for potential transplant recipients and living donors (if they perform living donor transplants). In addition, it is standard medical practice to document in the medical record of a hospital patient undergoing surgery whether the patient meets the hospital's criteria for surgery. Thus, we believe that the activities required by this section constitute usual and customary business practices for transplant centers. Therefore, pursuant to 5 CFR 1320.3(b)(2), we will not include these activities in the burden analysis for this final rule.

Section 482.92 Condition of Participation: Organ Recovery and Receipt

Transplant centers must have written protocols to validate donor-recipient matching of blood types and other vital data for deceased organ recovery, organ receipt, and living donor transplantation process.

The burden associated with this section is the time required to develop these written protocols. We believe that developing written protocols for critical functions such as those required by this section reflect usual and customary business practice for transplant centers. Therefore, the burden of these requirements is exempt under 5 CFR 1320.3(b)(2).

Section 482.94 Condition of Participation: Patient and Living Donor Management

Transplant centers must have written patient management policies for the transplant and discharge phases of transplantation. If a transplant center performs living donor transplants, the center also must have written donor management policies for the donor evaluation, donation, and discharge phases of living organ donation.

The burden associated with these requirements is the time it takes to develop written patient management policies. We believe that it is usual and customary business practice for

transplant centers, as it would be for any major health care facility, to have written patient management policies. Thus, under 5 CFR 1320.3(b)(2), these activities should be excluded from any burden analysis.

In addition, § 482.94(b) requires that transplant centers must keep their waiting lists up to date on an ongoing basis, including:

(1) Updating of waiting list patients' clinical information;

(2) Removing patients from the center's waiting list if a patient receives a transplant or dies, or if there is any other reason that the patient should no longer be on a center's waiting list; and

(3) Notifying the OPTN no later than 24 hours after a patient's removal from the center's waiting list.

Section 482.94(c) requires transplant centers to maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a center's waiting list and who is admitted for organ transplantation.

Section 482.94(c)(1) states that for each patient who receives an evaluation for placement on a center's waiting list, the center must document in the patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) has been informed of his or her transplant status, including notification of: (i) The patient's placement on the center's waiting list; (ii) The center's decision not to place the patient on its waiting list; or (iii) The center's inability to make a determination regarding the patient's placement on its waiting list because further clinical testing or documentation is needed.

Section 482.94(c)(2) states that if a patient on the waiting list is removed from the waiting list for any reason other than death or transplantation, the transplant center must document in the patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) was notified of his or her removal from the waiting list no later than 10 days after the date the patient was removed from the center's waiting list.

Section 482.94(c)(3) states that in the case of patients admitted for organ transplants, transplant centers must maintain written records of multidisciplinary patient care planning during the transplant period and multidisciplinary discharge planning for post-transplant care.

The burden associated with this section, except for notifying dialysis facilities, is the time required for a transplant center to document all the necessary information and maintain the waiting list. As described above, all transplant centers must already follow OPTN requirements for notification of patients and maintenance of their waiting lists. We believe that most, if not all, transplant centers have business practices that already comply with this section. For the remainder of centers, compliance should require only a minimal burden.

Under 5 CFR 1320.3(b)(2), if the activities that are needed to comply with an ICR constitute usual and customary business practices, those activities should be excluded from the burden analysis. Since the activities that are required to satisfy this section constitute usual and customary business practices, the burden associated with them will not be included in our PRA analysis for this final rule.

Section 482.94(c)(1) and (2) require kidney transplant centers, in the case of dialysis patients, to document in the patient's record that both the patient and the patient's usual dialysis facility have been notified of the patient's transplant status and all changes in the patient's transplant status as required under § 482.94(c)(1). Since this is not a requirement for OPTN members, we do not believe that all kidney transplant centers are currently notifying dialysis facilities.

The burden associated with this requirement is the time it would take for the transplant center to notify the various dialysis facilities of the status of their patients on the transplant center's waiting list. Rather than notifying dialysis facilities on an individual basis, we believe that transplant centers would chose to periodically notify the dialysis centers about their patients' status. Thus, for the purposes of determining the burden for this requirement, we will assume quarterly notifications by the transplant centers to the dialysis facilities. Note that this final rule does not establish a time frame transplant centers must use to notify dialysis centers about patient status. We are using quarterly notification only to estimate an economic impact for this notification requirement.

According to UNOS, as of December 31, 2005, there were 64,848 individuals awaiting kidney transplants. Currently, there are approximately 4,649 dialysis facilities and approximately 243 Medicare-approved kidney transplant centers. Therefore, the average transplant center will have to notify 19 dialysis clinics about the waiting list status of their patients (4,649 dialysis facilities divided by 243 Medicare-approved kidney transplant centers = 19.13 dialysis centers). Since there are 64,848 patients waiting for kidney transplants and 4,649 dialysis facilities, there are an average of 14 patients on the waiting list for kidneys at each dialysis facility (64,848 patients divided by 4,649 dialysis facilities = 13.9). Thus, for each of the 243 kidney transplant centers, there are about 267 waiting list patients (64,848 patients divided by 243 transplant centers = 266.86 or 14 patients per dialysis facility $\times$ 19 dialysis facilities = 266). Therefore, on average, each transplant center would have to determine the status of about 267 patients and notify an average of 19 dialysis facilities about the status of these patients 4 times a year.

Based upon our past experience, we believe that this notification would require the involvement of the transplant coordinator and appropriate support/clerical staff. We would anticipate that the transplant centers would utilize modern technology to minimize the burden of satisfying this requirement.

TOTAL ANNUAL BURDEN HOURS AND TOTAL ANNUAL COST ESTIMATE TO NOTIFY DIALYSIS FACILITIES OF THEIR PATIENTS' WAITING LIST STATUS

Position	Hourly wage	Burden hours per event*	Cost estimate per event*	Total annual hours required (for 4 events)	Total annual cost estimate (for 4 events)
Transplant Coordinator	$ 43.87	2.00	$87.74	8.0	$350.96
Secretary	21.81	.50	10.90	2.0	43.62
Totals	.....	2.50	98.64	10.0	394.58

All salary information is from the salary.com Web site at *http://hrsalarycenter.salary.com.*
*Each notification is an ''event.''

Thus, we anticipate that the burden hours for each time a transplant center notifies the relevant dialysis centers of the status of their patients on the center's waiting list would require 2.5 burden hours and the cost estimate would be $98.64. With the transplant centers conducting these notifications on a quarterly basis, that is, 4 notifications per year for each kidney center, the total annual burden hours for each center would be 10 and the total annual cost estimate would be $394.58. Since there are currently 243 current Medicare-approved kidney transplant centers, their total burden hours would be 2,430 (243 centers × 10 hours = 2,430) and the total cost complying with this ICR is $95,882.94 (243 centers × $394.58 = $95,882.94).

Section 482.96 Condition of participation: Quality assessment and performance improvement (QAPI)

Section 482.96 requires transplant centers to develop, implement, and maintain a written, comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all transplantation services, including services provided under contract or arrangement.

Section 482.96(b) requires transplant centers to establish and implement written policies to address and document adverse events that occur during any phase of an organ transplantation case. These policies must address, at a minimum, the process for the identification, reporting, analysis, and prevention of adverse events. When an adverse event is identified, the transplant center must conduct a thorough analysis of and document any adverse event.

The burden associated with this rule is the time required to develop these policies and document each adverse event. In the proposed rule, we estimated that it would take 8 hours on a 1-time basis to comply with this requirement.

Comment: Some commenters disagreed with our analysis and said that we underestimated the time and staff hours required to comply with this section. One commenter stated that a large center would require one full-time equivalent (FTE) to comply with this requirement. Another commenter indicated that it took 160 staff hours to develop and establish the QAPI program at his or her hospital and 1.25 FTEs to maintain the program. This commenter indicated that eight hours would only be a ''start'' in complying with this requirement.

Response: We agree with the commenters that 8 hours is insufficient to develop the policies necessary to comply with this section. However, since all transplant centers are located in Medicare hospitals and Medicare hospitals are required to have a QAPI program (see 42 CFR 482.21), we believe that each center will have sufficient resources available to develop its own QAPI program in considerably fewer than 160 burden hours.

We believe that the typical transplant center would already have established a QAPI program as part of its usual and customary business practices and, thus, would not incur any additional associated burden. Therefore, since the activities required to comply with this section constitute usual and customary business practices, any burden associated with this requirement is exempt from the burden analysis under 5 CFR 1320.3(b)(2).

Section 482.98 Condition of Participation: Human Resources

Section 482.98(b) requires transplant centers to identify to the OPTN a primary transplant surgeon and a transplant physician with the appropriate training and experience to provide transplantation services who are immediately available to provide transplantation services when an organ is offered for transplantation.

The burden associated with this requirement is the time it will take to compile this information and forward it to the OPTN. Since this same information is required for the letter requesting initial approval for the transplant center at § 488.61(a), each transplant center will only need to notify the OPTN of the two individuals it has designed as its primary transplant surgeon and transplant physician. This could be done electronically or by a simple form, depending upon OPTN requirements. Thus, notifying the OPTN of the same information should not result in any additional appreciable burden to the transplant centers.

Section 482.100 Condition of Participation: Organ Procurement

Section 482.100 requires a transplant center to ensure that the hospital in which it operates has a written agreement for the receipt of organs with an OPO designated by the Secretary that identifies specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation.

The burden associated with this rule is the time required to draft a mutually acceptable agreement between the transplant center and the designated OPO for the receipt of organs. Section 121.9 of the Department's regulations governing the OPTN requires transplant centers to have letters of agreement or contracts with an OPO. However, such a letter of agreement or contract will not satisfy the requirements of this section if it does not identify specific responsibilities for the hospital and the OPO with respect to organ recovery and organ allocation. Thus, we believe that approximately 50 percent, or 252, transplant centers will need to re-draft the letters of agreement or contracts between themselves and their designated OPOs that identify specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation.

Based upon our experience with transplant centers, as well as other health care organizations, agreements of this type would require the involvement of the transplant center's attorney, medical director, administrator, transplant coordinator, and appropriate clerical/support staff. We believe that it would require a total of approximately

11 hours to negotiate and draft a mutually acceptable agreement that would be signed by both the transplant center and OPO.

TOTAL ANNUAL BURDEN HOURS AND TOTAL ANNUAL COST ESTIMATE TO DEVELOP AN AGREEMENT BETWEEN A TRANSPLANT CENTER AND AN OPO CONCERNING ORGAN RECOVERY AND ORGAN ALLOCATION

Position	Hourly wage	Total annual hours required	Total annual cost estimate
General Counsel or Attorney	$176.86	4.0	$707.44
Medical Director	116.60	2.0	233.20
Senior Administrator	92.31	2.0	184.62
Transplant Coordinator	43.87	2.0	87.74
Secretary	21.81	1.0	21.81
Totals	.....	11.00	1,234.81

All salary information is from the salary.com Web site at *http://hrsalarycenter.salary.com*.

Thus, for each transplant center to negotiate and draft an agreement with its designated OPO concerning organ recovery and organ allocation, the total annual burden hours would be 11 and the total cost estimate would be $1,234.81. For 252 transplant centers to negotiate and draft these agreements, the total burden hours would be 2772 (11 annual burden hours × 252 transplant centers = 2,268) and the total cost estimate would be $311.172.12 (252 transplant centers × $1,073.30).

Section 482.102 Condition of Participation: Patient and Living Donor Rights

Section 482.102 requires transplant centers to implement written transplant patient informed consent policies. The policies must inform each patient of: (1) The evaluation process; (2) the surgical procedure; (3) alternative treatments; (4) potential medical or psychosocial risks; (5) national and transplant center-specific outcomes; (6) organ donor risk factors that could affect the success of the graft or the health of the patient, including, but not limited to, the donor's history, condition or age of the organs used, or the patient's potential risk of contracting the human immunodeficiency virus and other infectious diseases if the disease cannot be detected in an infected donor; (7) his or her right to refuse transplantation; and (8) the fact that if his or her transplant is not provided in a Medicare-approved transplant center, it could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid under Medicare Part B.

Section 482.102(b) also requires transplant centers to implement written living donor informed consent policies that inform the prospective living donor of all aspects of, and potential outcomes from, living donation. Each transplant center must ensure that the prospective living donor is fully informed about the following: (1) The fact that communication between the donor and the transplant center will remain confidential; (2) the evaluation process; (3) the surgical procedure, including post-operative treatment; (4) the availability of alternative treatments for the transplant recipient; (5) the potential medical or psychosocial risk to the donor; (6) the national and transplant center-specific outcomes for recipients; and national and center-specific outcomes for living donors, as data are available; (7) the possibility that future health problems related to the donation may not be covered by the donor's insurance and that the donor's ability to obtain health, disability, or life insurance may be affected; (8) the donor's right to opt out of donation at any time during the donation process; and (9) the fact that if a transplant is not provided in a Medicare-approved transplant center, it could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid under Medicare Part B.

We expect that nearly all transplant centers currently have written policies regarding informed consent. Therefore, there would be no additional burden on them, as these policies are usual and customary business practices. Therefore, the burden of these requirements is exempt under 5 CFR 1320.3(b)(2) and will not be included in our PRA analysis for this final rule.

Section 482.102(c) requires each transplant center to notify patients placed on its waiting list of information about the center that could impact the patient's ability to receive a transplant should an organ become available, and what procedures are in place to ensure the availability of a transplant team. Section 482.102(c)(1) specifically requires a transplant center served by a single transplant surgeon or physician to inform patients placed on the center's waiting list of the potential unavailability of the transplant surgeon or physician and whether the center has a mechanism to provide an alternative transplant surgeon or transplant physician.

Comment: One commenter pointed out that complying with this requirement would entail the drafting of a letter by an administrator, approval by the surgeon, searching a database to identify appropriate patients, clerical or support resources to prepare and mail the letters, and the expense associated with actually mailing the letters. The commenter pointed out that this would be an extensive and unrealistic use of resources for short-term unavailability issues, such as the absence of the transplant surgeon.

Response: As discussed earlier in this preamble, this provision does not require transplant centers to inform waiting list patients on an ongoing basis about the short-term unavailability of a transplant surgeon, for example, when a transplant surgeon is on vacation. The provision simply requires that, at the time a patient is placed on the waiting list, the patient is informed about circumstances that could impact the patient's ability to receive a transplant should an organ become available and what procedures the transplant center has in place to address these circumstances. Clearly, this requirement is particularly important when a transplant center is served by a single transplant surgeon or transplant physician. We expect that most transplant centers already provide this information to patients when they are placed on the waiting list.

Therefore, the burden associated with this requirement is exempt under 5 CFR 1320.3(b)(2). The burden of these activities will not be included in our PRA analysis for this final rule.

Section 482.102(c)(2) states that at least 30 days before a transplant center's Medicare approval is terminated, whether voluntarily or involuntarily,

the center must inform patients on the center's waiting list of this fact and provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list. The transplant center must also inform Medicare beneficiaries on the center's waiting list that Medicare will no longer pay for transplants performed at the center after the effective date of the center's loss of Medicare approval at least 30 days before their Medicare approval is terminated. In addition, § 482.102(c)(3) requires that as soon as possible prior to a transplant center's voluntary inactivation, the center must inform patients on the center's waiting list and, as directed by the Secretary, provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without the loss of time accrued on the waiting list.

The burden associated with this section would be the time required of a transplant center to draft a letter notifying patients on its waiting list of the loss of the program's Medicare approval status and, by mail or otherwise, provide the letter to all patients on the center's waiting list. We estimate that it would require an administrator approximately 30 minutes to draft the letter. It would then require a secretary or other support staff person 2.5 hours to copy and/or mail these letters to the individuals on the center's waiting list(s). Based on our estimate, complying with this section would require three burden hours and the total cost would be $100.69.

TOTAL BURDEN HOURS AND TOTAL COST ESTIMATE FOR NOTIFYING PATIENTS ON A CENTER'S WAITING LIST OF A TRANSPLANT CENTER'S LOSS OF MEDICARE APPROVAL

Position	Hourly wage	Hours required	Total cost estimate
Senior Administrator	$92.31	.50	$46.16
Secretary	21.81	2.50	54.53
Totals	.....	3.00	100.69

All salary information is from the salary.com Web site at *http://hrsalarycenter.salary.com*.

As discussed in more detail below under section § 488.61, we believe that, based upon the requirements contained in this final rule, up to two percent of transplant centers or approximately 10 centers may lose their Medicare-approved status annually. If 10 centers annually lost their Medicare-approved status, either voluntarily or involuntarily, then the total annual burden hours would be 30 (10 transplant centers × 3 burden hours = 30 total burden hours) and the total annual cost estimate would be $1,006.90 ($100.69 cost estimate × 10 transplant centers = $1,006.90).

Section 482.104 Condition of Participation: Additional Requirements for Kidney Transplant Services

Section 482.104(a) states that a kidney transplant center must have written policies and procedures for ongoing communications with dialysis patients' local dialysis facilities.

The burden associated with this requirement is the time and effort it would take for a kidney transplant center to develop the written policies and procedures for such communication. Under this final rule, one of the responsibilities of the clinical transplant coordinator is to act as a liaison between a kidney transplant center and dialysis facilities. (See § 482.98(c)(2).) We believe that most centers currently use their clinical transport coordinators in this role. Most centers will be able to meet this requirement by putting their current practice into writing. This will probably be done by the clinical transplant coordinators. Since they are memorializing their current practices, we believe it can be accomplished in a very short time. We believe that this communication policy and procedures will be straightforward and can be accomplished quickly by the coordinators. In addition, many centers may already have such policies and procedures in writing. Thus, complying with this requirement will constitute a minimal burden to the centers.

Section 488.61 Special Procedures for Approval And Re-Approval of Organ Transplant Centers

Section 488.61(a) requires transplant centers that are not Medicare-approved as of June 28, 2007 to submit a request to CMS for Medicare approval. Section 488.61(b) requires transplant centers, including kidney transplant centers, that are Medicare approved as of June 28, 2007 to submit a request for Medicare approval no later than December 26, 2007. The process for making the request for Medicare approval is the same for both types of transplant centers. (See § 488.61(b)(1).) The request for Medicare approval must be signed by a person authorized to represent the center (for example, a chief executive officer). The request must include the hospital's Medicare provider identification (I.D.) number; the name(s) of the designated primary transplant surgeon and primary transplant physician; and a statement from the OPTN that the center has complied with all data submission requirements.

The burden associated with this section would be the time required to prepare and submit this letter to us. In addition, the center would have to obtain a statement from the OPTN that the center had complied with all data submission requirements to submit with the letter.

In the proposed rule, we estimated that each hospital would spend approximately 15 minutes to prepare and submit the letter requesting Medicare approval to us. We did note that a hospital may have multiple transplant centers and, therefore, could be submitting more than one request for approval.

Comment: We received public comments on the proposed rule that said we had underestimated the time required for a transplant center to apply for Medicare approval. One commenter emphasized that transplantation centers take applying for Medicare approval very seriously. The commenter also indicated that the preparation, approval, and submission of the request for Medicare approval could take days at many large institutions.

Response: After further analysis of the tasks and the personnel that would be involved in applying for Medicare approval, we agree with the commenters that 15 minutes significantly underestimates the time required to prepare, obtain the required center approval(s), obtain the statement from

the OPTN, and submit the request for Medicare approval to us. However, we disagree with the commenter that said it could take ''days'' to accomplish all of the required tasks. Our analysis of the total burden hours and total cost estimate are discussed in detail below.

We now believe that accomplishing all of the tasks necessary for complying with § 488.61(a) would involve the transplant program's medical director, an administrator, a transplant coordinator, and appropriate support/administrative staff. We estimate that it would take these individuals approximately the same amount of time as it would take the transplant center to notify us of a significant change in their program or approximately 2 burden hours.

TOTAL ANNUAL BURDEN HOURS AND TOTAL ANNUAL COST FOR A TRANSPLANT CENTER TO APPLY FOR MEDICARE APPROVAL

Position	Hourly wage	Hours required	Total cost estimate
Medical Director	$116.60	.50	$58.30
Senior Administrator	92.31	.50	46.16
Transplant Coordinator	43.87	.75	32.90
Secretary	21.81	.25	5.45
Totals	.....	2.00	142.81

All salary information is from the salary.com Web site at*http://hrsalarycenter.salary.com.*

This final rule requires all transplant centers that are currently Medicare-approved to apply for initial approval under the requirements in this final rule. There are currently approximately 504 Medicare-approved transplant centers. We believe that all 504 transplant centers will submit requests to us to retain their Medicare approval. In addition, based on our previous experience, we believe that approximately 10 new centers a year may apply for Medicare approval. Thus, we anticipate 514 transplant centers will be applying for Medicare approval of their transplant programs in the first year following the effective date of this final rule.

For the first year after the effective date of this final rule, the total burden hours would be 1,028 (514 transplant centers × 2 burden hours = 1,028 total burden hours), and the total cost estimate would be $73,404.34 (514 transplant centers × $142.81 = $73,404.34). For subsequent years, we anticipate that about 10 transplant centers will request initial Medicare approval. For those subsequent years, the total burden hours are 20 (10 transplant centers × 2 burden hours = 20 total burden hours) and the total cost estimate would be $1,428.10 (10 transplant centers × $142.81 = $1,428.10).

Section 488.61(d) allows transplant centers that have lost their Medicare approval to seek re-entry into the Medicare program at any time. A center that has lost its Medicare approval must:

(1) Request initial approval using the procedures at § 488.61(a);

(2) Be in compliance with §§ 482.72 through 482.104, except for § 482.82 (Re-approval Requirements), at the time of the request for Medicare approval; and

(3) Submit a report to us documenting any changes or corrective action(s) taken by the center as a result of the loss of its Medicare approval status.

The burden associated with this section would be the time required to prepare and submit the request for approval to us pursuant to § 488.61(a) and the time to prepare and submit a report to CMS documenting any changes or corrective actions taken by the center as a result of the loss of its Medicare approval status. After further analysis of the tasks that would be involved and the personnel that would be needed, we believe that developing and submitting the required plan would involve the transplant program's medical director, an administrator, a transplant coordinator, and appropriate support/administrative staff.

In the proposed rule, we said that we believed no more than 9 entities would be affected by this requirement which made it exempt from the PRA, in accordance with 5 CFR 1320.3(c). This was based on our previous experience with transplant centers. Previously, only five centers had voluntarily terminated their Medicare approval.

However, this final rule has minimum clinical experience, outcome, and process requirements that transplant centers must meet to obtain initial Medicare approval and to stay in the program. Considering these requirements, we anticipate that more centers may voluntarily terminate their Medicare approval status in order to give themselves time to correct any problems they may have in meeting these requirements. In addition, it may become more common for transplant centers to be involuntarily terminated. Therefore, we estimate that up to two percent or approximately 10 of the currently Medicare-approved centers may lose their status at some point in any given year and later seek to re-enter the program.

We believe that accomplishing all of the tasks necessary for complying with § 488.61(d) would require the same staff as needed for § 488.61(a) and (b). However, we also believe that the center requesting re-entry into the Medicare program will spend more time preparing the request due to the preparation of the report documenting any changes or corrective action taken by the center as a result of the loss of its Medicare approval status. Thus, we believe that a transplant center complying with this sub-section's requirements would require a total of 5 burden hours and have a total cost estimate of $329.50. In any given year, we anticipate as many as 10 centers may seek to re-enter the Medicare program. For these 10 centers, the total burden hours would be 50 (10 centers × 5 burden hours to re-apply = 50 total burden hours) and the total cost estimate would be $3,295.00($329.50 per center to re-apply × 10 centers = $3,295.00).

TOTAL ANNUAL BURDEN HOURS AND TOTAL ANNUAL COST FOR TRANSPLANT CENTERS SEEKING RE-ENTRY INTO THE MEDICARE PROGRAM AFTER LOSS OF MEDICARE APPROVAL

Position	Hourly wage	Hours required	Total cost estimate
Medical Director	$116.60	1.00	$116.60
Senior Administrator	92.31	1.00	92.31
Transplant Coordinator	43.87	2.50	109.68
Secretary	21.81	.50	10.91
Totals	.....	5.00	329.50

All salary information is from the salary.com Web site at *http://hrsalarycenter.salary.com.*

Thus, for all of the PRA requirements in this rule, the total burden hours for the first year are 8,830, and the total cost estimate is $659,989.50. For subsequent years the total burden hours are 5,554 and the total cost estimate is $317,541,66. The burden hours and cost estimate are detailed in the chart below. All of the PRA requirements noted in this chart constitute new collections of information.

SUMMARY OF PRA REQUIREMENTS FOR TRANSPLANT CENTERS (TCS) IN THE FIRST YEAR OF THIS FINAL RULE

PRA requirement	Total annual cost estimate per TC	Total annual burden hours (BHs) per TC	Total annual cost estimate for "X" TCs	Total annual burden hours (BHs) for "X" TCs
§ 482.74—Notification to CMS of Significant Changes.	$428.43	6.0	$215,928.72 for 504 TCs (currently there are 504 Medicare approved TCs).	3,024 BHs for 504 TCs (currently there are 504 Medicare approved TCs).
§ 482.94(c)(3)—Notification to Dialysis Facilities of Patients' Waiting List Status.	394.58	10.0	$95,882.94 for 243 TCs (currently there are 243 Medicare-approved kidney TCs).	2,430 BHs for 243 TCs (currently there are 243 Medicare-approved kidney TCs).
§ 482.100—Development of Agreement Between T.C. and Each OPO on Organ Recovery and Allocation [1].	1,234.81	11.0	$311,172,12 for 252 TCs (we estimate that about 50 percent, or 252, TCs will need to re-draft letters of agreements of contracts between themselves and their designated OPOs).	2,772 BHs for 252 TCs (we estimate that about 50 percent, or 252, TCs will need to re-draft letters of agreements of contracts between themselves and their designated OPOs).
§ 482.102(c)(2)—Notification of Patients on Waiting List of Loss of Medicare Approval.	100.69	3.0	$1,006.90 for 10 TCs (we estimate that about 10 TCs would lose their Medicare Approval each year).	30 BHs for 10 TCs (we estimate that about 10 TCs would lose their Medicare Approval each year).
§ 488.61(a)—Application for Medicare Approval [2].	142.81	2.0	$73,404.34 for 514 TCs (first year—all 504 currently Medicare-approved TCs would need to apply and we estimate that 10 new TCs would also apply for a total of 514 TCs applying for Medicare approval in the first year).	1,028 BHs for 514 TCs (first year—all 504 currently Medicare-approved TCs would need to apply and we estimate that 10 new TCs would also apply for a total of 514 TCs applying for Medicare approval in the first year).
§ 488.61(d)—Application to Re-Enter Medicare Program.	329.50	5.0	$3,295.00 for 10 TCs (we estimate that 10 TCs who had lost their Medicare approved status would seek to re-enter the Medicare Program each year)..	50 BHs for 10 TCs (we estimate that 10 TCs who had lost their Medicare approved status would seek to re-enter the Medicare Program each year).
Totals	2,630.82	37.0	700,690.02	9,334 BHs.

[1] These estimates are for the first year of implementation only. After the first year, we estimate that fewer than 10 transplant centers will need to comply with this requirement. Therefore, in subsequent years, this requirement would not be subject to the PRA.

[2] This estimate is for the first year only. In subsequent years, we estimate that only 10 new transplant centers will apply for Medicare approval each year. Thus, for subsequent years, the estimated burden hours will be 20 (2 BHs × 10 TCs) and the cost estimate will be $1,428.10 ($142.81 × 10 TCs).

If you comment on these information collection and record keeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attn.: Melissa Musotto, CMS–3835–F, Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Carolyn Lovett, CMS Desk Officer, CMS–3835–F, *carolyn_lovett@omb.eop.gov.* Fax (202) 395–6974.

V. Regulatory Impact Statement

A. Overall Impact

We have examined the impact of this final rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the

Regulatory Flexibility Act (RFA) (September 16, 1980 Public Law 96–354), Section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibilities of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if new regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate the overall economic impact of this final rule to be a cost of $28,420,259 and a benefit of $1,257,516 in the first year. The social benefits that should result from implementation of this final rule are significant. However, we have no reasonably accurate method of quantifying those social benefits. Thus, we do not believe that this final rule is economically significant.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, non-profit organizations, government agencies, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by non-profit status or by having revenues of $29 million or less in any 1 year (65 FR 69432). Individuals and states are not included in the definition of a small entity. We believe this rule will not have a significant impact on a substantial number of small businesses because most of the requirements in this final rule are already part of the transplant centers' standard practices.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area (superseded by Core Based Statistical Areas) and has fewer than 100 beds. We believe this final rule will not have a significant impact on small rural hospitals since small rural hospitals do not have the resources to perform organ transplants.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by state, local or tribal governments, in the aggregate, or by the private sector, of $110 million or more. We do not believe that this rule will have an effect on state, local or tribal governments, or the private sector, that could create an unfunded mandate greater than $110 million annually.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This rule does not impose substantial direct requirement costs on state or local governments and does not preempt state law or have other Federalism implications. We have determined that this final rule will not significantly affect the rights, roles, and responsibilities of states.

This final rule will affect all facilities that perform, or are planning to perform, organ transplants and may have an effect on the ability of those facilities to compete. Thus, while we do not believe the requirements will have a significant economic impact on these facilities, we believe it is desirable to inform the public of the likely effect of this final rule on those facilities. Thus, we have prepared the following analysis, which in combination with the other sections of this final rule, is intended to conform to the objectives of the RFA and section 1102(b) of the Act.

B. Anticipated Effects

Our intent in developing and implementing these CoPs for transplant centers is to ensure Medicare-covered transplants are performed in an effective, efficient manner and that high quality transplantation services are provided to Medicare beneficiaries. This is critical due to the scarcity of transplantable organs for the individuals on organ transplant waiting lists. This final rule also serves to keep Medicare requirements current with the best practices in transplantation. We believe that adherence to these outcomes and process requirements will result in reduced organ wastage and, as a consequence, fewer graft failures and re-transplantations. We do not anticipate that the changes in our requirements for transplant centers will affect the number of organ transplants performed because this final rule will have no effect on the number of organs available for transplantation.

This final rule will establish CoPs for transplant centers that perform organ transplants. The final rule will maintain many of the same requirements that are in the current National Coverage Decisions (NCDs) for heart, liver, lung, and intestine transplants, and conditions for coverage (CfCs) for kidney transplant centers in 42 CFR, Part 405, subpart U. Some of the requirements in this final rule could result in additional costs for some centers. Although we do not believe the requirements in this final rule will have a substantial economic impact on a significant number of transplant centers, we believe it is desirable to inform the public of our projections of the likely effects of this final rule. There are two reasons this final rule will have a minimal economic effect.

As of October 1, 2006, 504 Medicare-approved transplant centers potentially will be affected by the requirements in this final rule to a greater or lesser degree. However, we believe the majority of the transplant centers have already put into practice most of the process requirements contained in this final rule. Since these requirements, for the most part, reflect advances in transplantation technology, we believe they are routine or standard practices for most transplant centers. Furthermore, although this final rule requires a large amount of data to be submitted, transplant centers are already submitting these data to the OPTN.

General Comments

In the public comments to the proposed rule, some commenters said that CMS had underestimated the impact the requirements in the proposed rule would have on transplant centers. They stated that the number of hours and the costs associated with some requirements were either inaccurate or were underestimated.

We agree with the commenters that in certain instances the economic impact was underestimated in the proposed rule. We have performed further analysis of the tasks and resources required to satisfy the CoPs in this final rule, and we have reviewed more recent economic data. Based on this further analysis, we have adjusted our estimate of the economic impact for the final rule. These adjustments are discussed below for each relevant condition of participation.

Some commenters said that some of the CoPs in the proposed rule were unnecessary because some of the requirements are similar or even identical to either current OPTN or JCAHO requirements. We agree that

some of the CoPs are similar or perhaps even identical to OPTN or JCAHO requirements. However, for these requirements to be mandatory and enforceable by CMS through our survey and certification process, they must be promulgated as regulations.

Some commenters expressed concern that these new requirements would increase costs. One commenter noted that increased costs could result in increased organ acquisition fees and subsequent increased expenses to the Medicare program and could also reduce access to transplantation services for some individuals. The commenter speculated that hospitals could have difficulty contracting with managed care organizations due to the increased costs.

As we stated above, we do not believe this rule will have a significant economic impact on most transplant centers because most of the requirements are routine practice in the majority of centers. In addition, all transplant centers are located in hospitals and thus, already have access to resources that should minimize the additional costs needed to satisfy the requirements in this final rule. Only the costs associated with the donor advocate or donor advocate team requirements will affect organ acquisition fees. We estimate that in the first year of its implementation, the requirements in this final rule will increase the cost of a transplant by approximately $1,071 per transplant ($28,420,256 total first year costs divided by 26,539 total transplants in 2004 = $1,070.88 or about $1,071). However, in subsequent years, the increase will drop to approximately $360 per transplant (about 9,566,291 implementation costs in subsequent years divided by 26,539 total transplants in 2004 = $360.46 or approximately $360). In light of the fact that the total first-year cost of an organ transplant (including both hospital and physician charges) varies from about $175,000 for a kidney transplant to nearly $400,000 for a heart transplant, the impact of this rule will be negligible. Thus, hospitals should have no difficulty contracting with managed care organizations due to the requirements in this final rule.

Section 482.72 Condition of Participation: OPTN Membership

Section 482.72 requires each transplant center to be located in a transplant hospital that is a member of and abides by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN). Under § 482.45(b)(1) of the hospital CoPs, all transplant centers that are currently Medicare-approved are required to be located in hospitals that are members of the OPTN and that abide by the OPTN's rules. Thus, there is no additional burden or economic impact associated with this condition to centers that currently have Medicare approval. Since this final rule requires centers to perform a certain number of transplants prior to applying for Medicare approval, new centers also will be members of the OPTN. Thus, there is no economic impact from this requirement to centers that will be applying for Medicare approval after the effective date of this rule.

Section 482.74 Condition of Participation: Notification to CMS

Section 482.74 requires a transplant center to notify us immediately of any significant changes related to the center's transplant program or changes that could affect its compliance with the applicable CoPs. Instances in which CMS should be notified include, but are not limited to, changes in key staff members of the transplant team; a decrease in the center's number of transplants or survival rates that could result in the center being out of compliance with § 482.82; termination of an agreement between the hospital in which the transplant center is located and an OPO for the recovery and receipt of organs; and inactivation of the transplant center.

We believe that satisfying this requirement would require the involvement of the program's medical director, an administrator, a transplant coordinator, and appropriate support or administrative staff. Based upon our previous experience with transplant centers, we believe that three significant changes per year per center is an appropriate estimate. We also believe that it would take the above described personnel approximately 2 hours to comply with this section.

Thus, each time a transplant center is required to report a significant change to us, the total economic impact or cost estimate is $142.81. For the estimated three significant changes per transplant center per year, the total cost estimate would be $428.43. Since there are currently approximately 504 Medicare-approved transplant centers, the total annual cost estimate for complying with this section is $215,928.72 ($428.43 annual cost estimate per center × 504 transplant centers = $215,928.72).

Section 482.76 Condition of Participation: Pediatric Transplants

Section 482.76 requires transplant centers that want Medicare approval to provide transplant services to pediatric patients to submit to us a request specifically for Medicare approval to perform pediatric transplants using the procedures described in § 488.61, Special procedures for approval and re-approval of organ transplant centers. Section 482.76(d) allows heart transplant centers that want to provide transplantation services to pediatric heart patients to be approved to perform pediatric heart transplants by meeting the OBRA 1987 criteria in section 4009(b) (Pub. L. 100–203) as follows: (1) The center's pediatric transplant program must be operated jointly by the hospital and another facility that is Medicare-approved; (2) the unified program shares the same transplant surgeons and quality improvement program (including oversight committee, patient protocol, and patient selection criteria); and (3) the center demonstrates to the satisfaction of the Secretary that it is able to provide specialized facilities, services, and personnel that are required by pediatric heart transplant patients.

We believe that most transplant centers that want to obtain Medicare approval to do pediatric transplants will use the procedures at § 488.61. Therefore, the economic impact for centers requesting approval to do pediatric transplants will be discussed under that section. For those centers that want to request approval using the alternative criteria, we believe there will be some impact, but it will be minimal and should affect very few centers. Currently, there are approximately 13 pediatric heart centers; 6 of these centers are Medicare approved. Based on these figures, we expect that no more than one pediatric heart center will apply for Medicare approval per year.

Section 482.80 Condition of Participation: Data Submission, Clinical Experience, and Outcome Requirements for Initial Approval of Transplant Centers

Section 482.80 requires that transplant centers must generally meet all data submission, clinical experience, and outcome requirements to be granted initial approval by CMS. Section 482.80(a) states that no later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of the required data on all transplants, (deceased and living donors) it has performed. The required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration and follow-up, and living donor registration and follow-up. However, transplant centers already

submit these data to the OPTN, using the time frame specified by the OPTN, as required by 42 CFR 121.11, which regulates transplant hospitals' submission of data to the OPTN. Therefore, there is no additional cost to transplant centers from the data submission requirement in this final rule. Section 482.80(b) establishes a clinical experience requirement of 10 transplants in a 12-month period for initial Medicare approval for heart, intestine, kidney, liver, and lung transplant centers. The clinical experience requirement for initial approval for kidney centers is 3 transplants in a 12-month period. (See § 482.80(d)(5).)

Current national coverage decisions require 10 transplants for intestine and lung centers and 12 transplants for liver and heart centers. Current conditions for coverage for kidney transplant centers require 15 or more kidney transplants annually for a center to have unconditional status. Thus, all currently approved transplant centers should be performing the minimum number of transplants required.

Furthermore, even if a center does not meet the clinical experience requirements, we may grant the center initial Medicare approval based on a review of the center's compliance with the relevant conditions of participation at § 482.72 through § 482.76 and § 482.90 through § 482.104. (See § 488.61(a)(3).)

Nevertheless, some centers may not be granted Medicare approval due to their failure to satisfy the clinical experience requirements. Loss of Medicare approval is likely to result in the center losing patients. If a center with current Medicare approval applies for and is denied Medicare approval under this final rule, it has the option to leave the Medicare program voluntarily until it can satisfy the requirements.

Although we believe the economic impact of the clinical experience requirements will be minimal, we are not aware of any research that quantifies the cost or benefit to a hospital of having a transplant center. Anecdotal information indicates that some hospitals with a transplant center lose money or break even but that some hospitals experience a financial benefit. Whether a transplant center is a benefit or a cost to a hospital may depend at least in part on the type of organ transplanted, the volume of transplants performed, and the center's operational efficiency.

We also recognize that there may be benefits and/or costs to Medicare beneficiaries and other patients on the waiting lists of centers that lose Medicare approval, although we do not believe it is possible to quantify the benefits or costs. Benefits would include improved patient safety and better outcomes for patients who transfer to the waiting lists of transplant centers that furnish higher quality transplantation services. Costs could include increased cost for transportation to a center that is farther from a waiting list patient's home and an increase in the time until an organ becomes available, with the potential for increased morbidity and mortality.

Section 482.80(c) states that CMS will review outcomes for all transplants performed at a center, including outcomes for living donor transplants, if applicable. Except for lung transplants, CMS will review adult and pediatric outcomes separately when a center requests Medicare approval to perform both adult and pediatric transplants. Outcome data must be available for review. CMS will compare each transplant center's observed number of patient deaths and graft failures 1 year post-transplant to the center's expected number of patient deaths and graft failures 1-year post-transplant using the data contained in the most recent SRTR center-specific reports. (See § 488.61(d)(1).) The required number of transplants must have been performed during the time frame reported in the most recent SRTR center-specific report. (See § 488.61(c)(2).) CMS will not consider a center's patient and graft survival rates to be acceptable if: (1) A center's observed patient survival rate or observed graft survival rate is lower than its expected patient survival rate or expected graft survival rate; and (2) all three of the following thresholds are crossed over: (A) the one-sided p-value is less than 0.05, (B) the number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and (C) the number of observed events divided by the number of expected events is greater than 1.5. (See § 488.61(c)(3).)

Current national coverage decisions for heart, liver, lung, and intestine transplants already contain outcome requirements. However, those outcome requirements only concern patient (not graft) survival rates. The outcome requirements associated with § 482.80(c) are more comprehensive because they include graft survival. We believe that more centers may have difficulty in meeting these new standards. However, under § 488.61(a)(3), CMS, as an option, may approve a center that does not meet the patient and graft survival if a survey of the center demonstrates that the center was in compliance with § 482.72 through § 482.76 and § 482.90 through § 482.104. In addition, a center also may choose to withdraw voluntarily from the Medicare program and seek re-entry after it has corrected any problems. (See 42 CFR § 488.61(d).) Thus, we believe the economic impact from the new outcome measures will be minimal.

Section 482.82 Condition of Participation: Data Submission, Clinical Experience, and Outcome Measure Requirements for Re-Approval of Transplant Centers

Section 482.82 provides that transplant centers must generally meet all data submission, clinical experience, and outcome requirements in order to be re-approved. The data submission, clinical experience, and outcome requirements and exceptions to those requirements generally are identical to those in § 482.80, which contains the requirements for initial approval. However, in this section, the review will cover the 3-year approval period.

The economic impact of this section is the same as the economic impact of § 482.80, except that transplant centers will have to comply with these requirements for the entire time they have Medicare approval. Thus, the economic impact associated with this section constitutes an annual economic impact for all of the centers with Medicare approval. However, we believe the economic impact will be minimal.

Section 482.90 Condition of Participation: Patient and Living Donor Selection

Section 482.90 requires transplant centers to use written patient selection criteria in determining a patient's suitability for placement on the waiting list or a patient's suitability for transplant. If a center performs living donor transplants, the center also must use written donor selection criteria in determining the suitability of candidates for donation.

Section 482.90(a) requires that before a prospective transplant candidate is placed on a center's waiting list, each prospective transplant candidate shall receive a psychosocial evaluation, if possible. In addition, the candidate's medical record must contain documentation that the candidate's blood type has been determined. When a patient is placed on a center's waiting list or is selected to receive a transplant, the center must document in the patient's medical record the patient selection criteria used. A transplant center must provide a copy of its patient selection criteria to a transplant patient,

or a dialysis facility, as requested by the patient or the dialysis facility.

In our experience, all or nearly all transplant centers conduct psychosocial evaluations of transplant candidates. Such evaluations are performed routinely so that centers can evaluate how well a prospective candidate will do after transplantation (for example, whether the patient is likely to be compliant with the immunosuppressive medications needed to prevent graft failure). Thus, we expect no economic impact from this requirement for most transplant centers.

In the public comments we received on the proposed rule, some commenters said that the patient selection criteria requirements would be burdensome. For example, one commenter said that it would take at least 30 minutes of staff time to document the patient selection criteria in the file of each patient or living donor. Some commenters indicated that the patient selection criteria would need constant updating. They also noted that the proposed rule did not contain an analysis of the economic impact for this requirement.

We disagree that the requirement to have written patient selection criteria would have a significant impact on transplant centers. We expect that heart, liver, and lung transplant centers already have patient selection criteria because current NCDs require these centers to have such criteria. Further, Medicare coverage of pancreas and intestine transplants is based on specific clinical indicators. Although there are no current requirements for kidney transplant centers to have patient selection criteria, based on our experience, we expect that all or nearly all centers already have such criteria because many kidney transplant centers provide their patient selection criteria to local dialysis facilities. Therefore, complying with this requirement should have no additional impact on heart, liver, and lung centers and only a minimal impact on other transplant centers.

We believe that transplant centers should be able to document the patient selection criteria in a patient's medical record in considerably less than 30 minutes. Generally, documenting the patient selection criteria in a patient's medical record should involve no more than tracking the patient's primary diagnosis and any co-morbid conditions to the appropriate patient selection criteria. Under this final rule, each center has the flexibility to determine the most expedient way to satisfy this requirement. Centers should be able to significantly reduce the resources needed to document the required information in the potential transplant recipient and living donor medical records by using electronic formats, forms, or checklists.

In addition, it is standard medical practice to document in the medical record of a hospital patient undergoing surgery whether the patient meets the hospital's criteria for surgery. Although we do not know how many prospective transplant candidates would be interested in requesting a copy of a transplant center's patient selection criteria, we believe that the activities required by this section would have a minimal economic impact on transplant centers. Supplying a copy of patient selection criteria to a dialysis facility at its request can be done electronically and should require only minimal effort. Thus, we believe that the activities required by this section would require no additional staff and have only a minimal economic impact on transplant centers.

Section 482.90(b) provides that transplant centers performing living donor transplants must ensure that each prospective living donor receives a medical and psychosocial evaluation prior to donation and must document in the living donor's medical records both the living donor's suitability for donation and that the living donor has given informed consent, as required under § 482.102.

We expect the economic impact of these living donor requirements to be minimal, as they are similar to the requirements for transplant patients discussed previously. Due to the potential risks associated with donation, we expect that every transplant center that performs living donor transplants already has criteria for the selection of living donors, as well as protocols that require a medical and psychosocial evaluation of the donor. In addition, as with any other surgical procedure, documenting a living donor's informed consent should be standard practice for any transplant center. Thus, we believe that these activities would constitute a minimal economic burden to centers that perform living donor transplants.

Section 482.92 Condition of Participation: Organ Recovery and Receipt

Transplant centers must have written protocols for validation of donor-recipient blood type and other vital data for the deceased organ recovery, organ receipt, and living donor organ transplantation processes. There are also specific requirements related to each of these processes, such as a requirement that the transplanting surgeon and another licensed health care professional at the transplant center must verify that the donor's blood type and other vital data are compatible with transplantation of the intended recipient prior to transplantation. (See § 482.90(b).)

We expect that all transplant centers already have written protocols for critical functions addressed within this section. Although some centers' protocols may need to be reviewed and revised so that they satisfy the requirements in this section, the economic impact will be negligible.

Section 482.94 Condition of Participation: Patient and Living Donor Management

Transplant centers must have written patient management policies for the transplant and discharge phases of transplantation. If a transplant center performs living donor transplants, the center also must have written donor management policies for the donor evaluation, donation, and discharge phases of living organ donation.

We expect that it is standard practice for transplant centers to have written policies for the evaluation, transplant, and discharge phases of transplantation. Thus, developing written policies for these areas should have no economic impact on most transplant centers. However, we acknowledge that some of the centers' written policies may need to be revised to satisfy the individual standards in this section. Thus, the economic impact of individual standards will be discussed below.

Section 482.94(a) states that a transplant center's patient and donor management policies must ensure that each transplant patient is under the care of a multidisciplinary patient care team coordinated by a physician throughout the transplant and discharge phases of transplantation. If the center performs living donor transplants, the same patient care requirement applies for living donors throughout the donor evaluation, donation, and discharge phases of donation.

We believe that it is a standard practice for hospitals to have patient management policies that cover both the in-patient stay and discharge planning. Thus, we expect that transplant centers already have patient and donor management policies for the transplant and the discharge phases of transplantation. Due to the potential risks to living donors, we expect that every transplant center that performs living donor transplants already has written policies that cover the evaluation of living donors. We acknowledge that publication of this final rule may cause some centers to

review or revise their policies to ensure that they are in compliance. However, the economic impact on these transplant centers will be minimal.

Section 482.94(b) requires that transplant centers must keep their waiting lists up to date on an ongoing basis, including: (1) Updating of waiting list patients' clinical information; (2) removing patients from the center's waiting list if a patient receives a transplant or dies, or if there is any other reason why the patient should no longer be on a center's waiting list; and (3) notifying the OPTN no later than 24 hours after a patient's removal from the center's waiting list.

We believe these activities are standard practice for most transplant centers. Transplant centers must keep their patients' clinical information updated to ensure that organ offers are made for patients appropriately, based on their clinical status. Further, the OPTN requires transplant centers to: (1) Remove a patient from the waiting list if the patient receives a transplant or dies; and (2) notify the OPTN within 24 hours of the patient's transplantation or death. Thus, there should be no economic impact on transplant centers from this requirement.

Section 482.94(c) requires transplant centers to maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a center's waiting list and who is admitted for organ transplantation.

Section 482.94(c)(1) states that for each patient who receives an evaluation for placement on a center's waiting list, the center must document in the patient's record that the patient has been informed of his or her transplant status, including notification of the patient's placement on the center's waiting list, the center's decision not to place the patient on its waiting list, or the center's inability to make a determination regarding the patient's placement on its waiting list because further clinical testing or documentation is needed.

Section 482.94(c)(2) states that if a patient on the center's waiting list is removed for any reason other than death or transplantation, the center must document in the patient's record that the patient was notified no later than 10 days after the date the patient was removed from the center's waiting list.

Section 482.94(c)(4) states that in the case of patients admitted for organ transplants, transplant centers must maintain written records of multidisciplinary patient care planning during the transplant period and multidisciplinary discharge planning for post-transplant care.

All transplant centers must follow OPTN requirements regarding notification of patients and maintenance of their waiting lists. If a patient on the waiting list is removed from the waiting list for any reason other than death or transplantation, § 482.94(c)(2) requires the transplant center to document in the patient's record that the patient was notified not later than 10 days after the date the patient was removed from the waiting list. The OPTN already requires this notification, and documentation of the patient's record would be usual and customary business practice. Since we expect that all transplant centers are already complying with this requirement, there should be no economic impact on transplant centers from this requirement of the final rule. Thus, we believe that transplant centers already comply with the requirements in § 482.94(c), with the exception of the requirement for notification of dialysis facilities. Therefore, there is no economic impact on transplant centers from these requirements.

Sections 482.94(c)(1) and (2) require kidney transplant centers, in the case of dialysis patients, to notify the patients' usual dialysis facility. Since this is not an OPTN requirement, we do not believe that all transplant centers currently notify dialysis facilities about this information. When a kidney transplant center must notify a patient within 10 days about a change in status, the transplant center could choose to inform the dialysis facility at the same time it notifies the patient. If it did, we believe the burden of complying with this requirement would be minimal. However, the transplant center also could choose to notify the dialysis facilities periodically about other changes in status.

For the purpose of estimating the economic impact, we will assume that rather than notifying dialysis facilities on a flow basis for each patient, transplant centers will update dialysis centers periodically about the status of all patients. Thus, for the purposes of determining the burden for this requirement, we will assume quarterly notifications by transplant centers to dialysis facilities.

According to the OPTN, as of December 31, 2005, there were 64,848 individuals awaiting kidney transplants. Currently, there are 4,649 dialysis facilities in the United States. Since the number of patients at these facilities varies greatly, the following analysis will use the average number of dialysis patients at a facility. There are currently approximately 243 Medicare-approved kidney transplant centers. Therefore, each transplant center has patients on its kidney transplant waiting list from an average of 19 (4,649 dialysis facilities divided by 243 Medicare-approved kidney transplant centers = 19.13) dialysis centers. Since there are 64,848 patients waiting for kidney transplants and 4,649 dialysis facilities, each transplant center has an average of 14 kidney waiting list patients at each dialysis facility (64,848 patients divided by 4,649 dialysis facilities = 13.9). For each of the 243 kidney transplant centers, there are about 267 patients (64,848 patients divided by 243 transplant centers = 266.86 or 14 patients per dialysis facility × 19 dialysis facilities = 266). Thus, on average, each transplant center will have to determine the status of about 267 patients and notify an average of 19 dialysis facilities about the status of these patients 4 times per year.

Based upon our past experience, we believe that this notification will require the involvement of the transplant coordinator and appropriate support/clerical staff. We anticipate that transplant centers will utilize modern technology to minimize the burden of satisfying this requirement.

TOTAL ANNUAL BURDEN HOURS AND TOTAL ANNUAL COST ESTIMATE TO NOTIFY DIALYSIS FACILITIES OF THEIR PATIENTS' WAITING LIST STATUS

Position	Hourly wage	Burden hours per event	Cost estimate per event	Total annual hours required (for 4 events)	Total annual cost estimate for 4 events)
Transplant coordinator	$43.87	2.00	$87.74	8.0	$350.96
Secretary	21.81	.50	10.90	2.0	43.62

TOTAL ANNUAL BURDEN HOURS AND TOTAL ANNUAL COST ESTIMATE TO NOTIFY DIALYSIS FACILITIES OF THEIR PATIENTS' WAITING LIST STATUS—Continued

Position	Hourly wage	Burden hours per event	Cost estimate per event	Total annual hours required (for 4 events)	Total annual cost estimate for 4 events)
Total	.....	2.50	98.64	10.00	394.58

All salary information is from the salary.com Web site at *http://hrsalarycenter.salary.com.*

Thus, we anticipate that each quarterly notification will cost about $98.64. With the transplant centers conducting these notifications on a quarterly basis (that is, 4 notifications per year for each kidney center), the total annual economic impact to each kidney transplant center would be $394.58. Since there are currently about 243 Medicare-approved kidney transplant centers, the total economic impact from this requirement will be $95,882.94 annually (243 transplant centers × $394.58 = $95,882.94).

Section 482.94(d) states that a transplant center must make social services, furnished by qualified social workers, available to transplant patients, living donors, and their families. A qualified social worker is an individual who meets licensing requirements in the State in which he or she practices and (1) has completed a course of study with specialization in clinical practice and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education, or, (2) is working as a social worker in a transplant center as of the effective date of this final rule and has served for at least 2 years as a social worker, 1 year of which was in a transplantation program, and has established a consultative relationship with a social worker who is qualified under § 482.94(d)(1).

Current policies for heart, liver, and lung transplants require facility commitment at all levels, including social service resources. We believe nearly all transplant centers already have a qualified social worker to provide social services. Further, we have been careful to retain an exception for bachelor's-prepared social workers so that transplant centers that employ these social workers do not have to replace them with master's-prepared social workers, if they were employed as social workers in the transplant center as of the effective date of this final rule and served for at least 2 years as a social worker, 1 year of which was in a transplantation program, and has established a consultative relationship with a social worker who is qualified under § 482.94(d)(1). Thus, satisfying this requirement would constitute a minimal economic impact for most, if not all, centers.

Section 482.94(e) states that transplant centers must make nutritional assessments and diet counseling services, furnished by a qualified dietician, available to all transplant patients and living donors. A qualified dietician is an individual who meets practice requirements in the State in which he or she practices, and is a registered dietician with the Commission on Dietetic Registration.

Some commenters said that this requirement was too expensive and burdensome. We disagree. Kidney transplant centers are required by ESRD CfCs at § 405.2171(c) to ensure patients receive nutritional services from a qualified dietician. Thus, all kidney centers currently should be providing these services to transplant patients and living donors. We expect that most extra-renal transplant centers provide nutritional services to transplant patients, because these patients have very specific nutritional needs. Some liver, lung, and intestine centers that transplant organs from living donors may need to obtain a dietician's services for their living donors if they do not already provide these services. However, since the number of living liver, lung, and intestine donors in 2004 totaled fewer than 400, we believe liver, lung, and intestine centers can obtain nutritional services for their living donors from dieticians already employed by the hospitals in which the centers are located at little cost to the center. Thus, we expect the economic impact to be minimal.

Section 482.96 Condition of Participation: Quality Assessment and Performance Improvement (QAPI)

Section 482.96 requires transplant centers to develop, implement, and maintain a written, comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all transplantation services, including services provided under contract or arrangement.

Section 482.96(a) states that the transplant center's QAPI program must use objective measures to evaluate the center's performance with regard to transplantation activities and outcomes. Outcomes may include, but are not limited to, patient and donor selection criteria, accuracy of the waiting list in accordance with the OPTN waiting list requirements, accuracy of donor and recipient matching, patient and donor management, techniques for organ recovery, consent practices, patient education, patient satisfaction, and patient rights. The transplant center must take actions that result in performance improvements and track performance to ensure that improvements are sustained.

Section 482.96(b) requires transplant centers to establish and implement written policies to address and document adverse events that occur during any phase of an organ transplantation case. These policies must address, at a minimum, the process for identification, reporting, analysis, and prevention of adverse events. When an adverse event is identified, the transplant center must conduct a thorough analysis of and document any adverse event. The center must then use this analysis to effect changes in its policies and practices in order to prevent repeat incidents.

In the proposed rule, we estimated that only a minority of centers did not already have a data-driven QAPI program. For those centers that would need to develop a QAPI program that would satisfy this requirement, we estimated that a center would likely utilize an experienced individual from its hospital QAPI staff. We used the salary of a registered nurse (RN) to estimate the economic impact, since many QAPI coordinators are RNs. We noted that the 2002 mean annual income of an RN was $42,730 and requested comments addressing whether transplant centers would be able to utilize individuals from the hospital's existing QAPI staff to develop and implement a QAPI program specific to the transplant center or whether transplant centers would need to hire additional staff in order to comply with this proposed requirement. We did not make a specific estimate of the economic burden; however, we estimated the PRA burden to be 8 hours

on a one-time basis to comply with this requirement.

Comment: Some commenters disagreed with the resources we believed would be required to satisfy this requirement. One commenter stated that a large center would require one FTE to comply with this requirement. Another commenter indicated that it took 160 staff hours to develop and establish the QAPI program at their hospital and 1.25 FTEs to maintain the program. This commenter indicated that 8 hours would be only a ''start'' in complying with this requirement. Others noted that the establishment, implementation, and maintenance of such a QAPI program would be much more complex and would require more resources.

Other commenters disagreed with our use of the 2002 mean annual RN salary of $42,730. One commenter noted that a budget of $42,000 would not cover their projected expenses to satisfy this requirement. Another commenter also noted that this was insufficient. They noted the nursing shortage and that most of the clinical coordinators who would be doing this work were generally both highly experienced and trained, and held either a bachelor's or master's degree. One commenter explicitly said that the average annual national RN salary was not the appropriate salary to use in estimating the burden associated with the QAPI requirement.

Another commenter cautioned us about assuming that the hospital's QAPI program would satisfy this requirement. The commenter stated that although a hospital QAPI program may be able to support a single transplant center, the scope and complexity of multiple transplant centers would require more resources.

Response: We acknowledge that we underestimated the economic impact of the QAPI requirement in the proposed rule. It clearly will take more than 8 hours to develop and implement the policies necessary to comply with this section. We also agree that the use of the 2002 mean annual national RN salary is inadequate. However, while we agree that a hospital QAPI program may be inadequate to fully support its transplant center, particularly if a hospital has multiple transplant centers, we believe that the hospital's QAPI program would be a substantial resource for the staff responsible for the transplant center's QAPI program.

We believe that many centers have already established and implemented a QAPI program that satisfies this final rule's QAPI requirement. However, some of the centers may need to review and revise their programs. We believe this will constitute only a minimal economic impact to those centers.

Some centers may need to develop and implement a QAPI program. Beginning in 2003, hospitals are required to have hospital-wide QAPI programs that involve all hospital departments. (See 42 CFR 482.20.) Therefore, we believe that no more than 20 percent of the 504 currently Medicare-approved centers (101 centers) will need either to develop and implement a QAPI program or substantially revise an existing program. We also believe that no more than 40 percent of the centers (202 centers) will need to perform moderate revisions to their programs so that they will satisfy the QAPI requirements in this final rule. However, since each center is located in a hospital, we believe that centers will have substantial resources to draw upon in developing their QAPI programs.

Based on our past experience, we believe it is likely that centers will utilize an experienced staff person, possibly an experienced RN with some knowledge of the transplant program. An individual with this experience would likely be paid approximately the same as a transplant nurse coordinator or about $91,456 annually. We have considerable experience providing guidance to OPOs in developing comprehensive QAPI programs, which has provided us with knowledge of how many staff resources are needed to implement or modify a data-driven QAPI program. We believe it will require 1 FTE for each one of the 101 centers that will need either to develop a QAPI program or perform substantial revision to an existing QAPI program. We believe it will require half of an FTE for each one of the 202 centers that will need to perform at least moderate revisions to their programs. The cost to the 101 centers that need 1 FTE would be $9,237,056 ($91,456 × 101 = $9,237,056), and the cost to the 202 centers that need a half FTE would be $9,237,056 ($91,456 divided by 2 = $45,728 and $45,728 × 202 centers = $9,237,056). The total economic impact of this requirement on the transplant centers would be $18,474,112 ($9,237,056 + $9,237,056 = $18,474,112).

This section also requires the centers to maintain their QAPI programs. We believe that having and maintaining a QAPI program should be considered standard practice by the transplant centers. Once the center's QAPI program is developed and implemented, we believe that maintaining it would have a minimal economic impact on the transplant centers.

Section 482.98 Condition of Participation: Human Resources

Section 482.98 states that transplant centers must ensure that all individuals who provide services and/or supervise services at the center, including individuals furnishing services under contract or arrangement, are qualified to provide or supervise such services. Section 482.98(a) requires each transplant center to be under the general supervision of a qualified transplant surgeon or qualified physician-director. This director need not serve full time and may also serve as the center's primary transplant surgeon or transplant physician. Section 482.98(b) requires transplant centers to identify to the OPTN a primary transplant surgeon and a transplant physician with appropriate training and experience to provide transplantation services, who are immediately available to provide transplantation services when an organ is offered for transplantation.

Any economic impact associated with these requirements should be minimal. The current regulations for kidney transplant centers already require renal transplant centers to be supervised by a qualified transplantation surgeon or qualified physician-director, and we expect most extra-renal transplant centers have a director who would be considered qualified under this final rule. The OPTN requires transplant centers to have transplant surgeons and physicians with specific qualifications, training, and experience, and we believe that in most transplant centers, the primary transplant surgeon and transplant physician are immediately available to provide transplantation services when an organ is offered for a patient.

Section 482.98(c) requires transplant centers to have a clinical transplant coordinator who is either a registered nurse or other licensed clinician who has experience and knowledge of transplantation and living donation issues. Based on our experience with transplant centers, we believe that all or nearly all centers already have a clinical transplant coordinator on staff to coordinate all patient care and management activities. Therefore, we do not believe that this requirement will constitute any additional burden for transplant centers.

Section 482.98(d) states that transplant centers that perform living donor transplantation must identify either an independent living donor advocate or an independent living donor advocate team to ensure the protection of the rights of living donors and prospective living donors. This

individual(s) must not be involved in transplantation activities on a routine basis.

Due to the potential risks living donors face, we believe it is crucial that living donors have an independent living donor advocate or advocate team. In addition, due to their growing numbers, there is an urgent need to provide this type of service for these living donors. According to the 2005 OPTN/SRTR Annual Report, in 2003, there were a total of 6,820 living donors. In 2004, there were a total of 7,002 living donors, of which 6,645 were living kidney donors, 323 were living liver donors, 28 were living lung donors, and 6 were living intestine donors.

In determining an economic impact for this requirement, it is important to note that the number of living donors at a particular transplant center varies greatly. In order to estimate the economic impact, we have determined the annual average number of living donors per center, based on the annual number of living kidney and living liver donors. Since there are so few living lung and intestine donors, we have not estimated the impact of this requirement on lung or intestine transplant centers.

There are currently about 243 Medicare-approved kidney transplant programs. However, 31 of those centers perform only pediatric kidney transplants. Based on our review of data from the SRTR, pediatric kidney centers transplant very few kidneys from living donors. However, nearly all of the 212 adult kidney transplant centers perform living kidney transplants. There are currently 90 Medicare-approved liver transplant centers. However, in 2005 only about 36 percent or about 32 of those centers performed living liver transplants. We expect that at least half of the kidney and liver centers that perform living donor transplants already have a donor advocate or donor advocate team that fulfills the requirements of this final rule. Thus, we will determine an estimate of the economic impact for this requirement based on 106 kidney transplant centers (half the number of currently Medicare-approved kidney transplant centers) and 16 liver transplant centers (half the number of currently Medicare-approved liver transplant centers that perform living transplants).

Although some centers may choose to develop an independent living donor advocate team, we believe that most centers will choose to have an independent living donor advocate. Most centers will probably choose either an RN or a social worker to fill this position. We believe that the total annual compensation for this position would be approximately $81,124, which is the median annual total compensation for a renal dialysis staff nurse. Due to the number of living kidney donors, we believe that on average each center will need to have 1 FTE for the independent living donor advocate position. Thus, the total annual economic impact to kidney transplant centers would be $8,599,144 ($81,124 × 106 transplant centers = $8,599,144). However, there are far fewer living liver transplants performed per transplant center. Although each center will vary in the number of transplants performed, we estimate that on average each center will need about half FTE for an independent living donor advocate. Thus, the total annual economic impact to the liver transplant centers will be $648,992 ($81,124 × .5 = $40,562 × 16 centers = $648,992). Thus, the total economic impact for this requirement is $9,248,136 ($8,599.144 + $648,992 = $9,248,136).

Section 482.98(e) states that transplant centers must identify a multidisciplinary transplant team and describe the responsibilities of each member of the team. The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology.

Current NCDs for heart, liver, and lung transplant centers require them to have multi-disciplinary transplant teams, and current CfCs for kidney transplant centers require them to have both social workers and dieticians. We believe that all transplant centers have identified their multidisciplinary transplant teams and described the responsibilities of each member of that team. Thus, we do not anticipate that this requirement will have any economic impact on centers.

Section 482.98(f) states that each transplant center must demonstrate availability of expertise in internal medicine, surgery, anesthesiology, immunology, infectious disease control, pathology, radiology, blood banking, and patient education as related to the provision of transplantation services. Current NCDs for heart, liver, and lung transplant centers have similar requirements. Since every transplant center is part of a larger hospital, we expect that all transplant centers already have access to expertise in all of these areas. Therefore, this requirement will result in no additional economic impact.

Section 482.100 Condition of Participation: Organ Procurement

Section 482.100 requires a transplant center to ensure that the hospital in which it operates has a written agreement for the receipt of organs with an OPO designated by the Secretary that identifies specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation.

Therefore, we expect that all centers have some type of written agreement or contract with an OPO. However, these agreements may not satisfy the requirements of this section. Thus, we believe that approximately 50 percent of the 504 centers or 252 centers would need to revise the agreements between themselves and their designated OPOs for the receipt of organs that identify specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation.

TOTAL ANNUAL BURDEN HOURS AND TOTAL ANNUAL COST ESTIMATE TO DEVELOP AN AGREEMENT BETWEEN A TRANSPLANT CENTER AND AN OPO CONCERNING ORGAN RECOVERY AND ORGAN ALLOCATION

Position	Hourly wage	Total annual hours required	Total annual cost estimate
General Counsel or Attorney	$176.86	4.0	$707.44
Medical Director	116.60	2.0	233.20
Senior Administrator	92.31	2.0	184.62
Transplant Coordinator	43.87	2.0	87.74
Secretary	21.81	1.0	21.81
Totals	.....	11.00	1,234.81

All salary information is from the salary.com Web site at *http://hrsalarycenter.salary.com*

Based on our experience with health care organizations, agreements of this type would require the involvement of the hospital's attorney and an administrator. It would also involve the transplant center's director, transplant coordinator, and appropriate clerical/support staff. We believe that it would require a total of approximately 11 hours to negotiate and draft a mutually acceptable agreement that would be signed by both the transplant center and the OPO.

For each hospital in which one of the 252 transplant centers is located, the total cost estimate to negotiate and draft an organ recovery and organ allocation agreement with its designated OPO is $1,234.81. The total cost estimate is $311,172.12 (252 transplant centers × $1,234.81 = $311,172.12).

Section 482.102 Condition of Participation: Patient and Living Donor Rights

Section 482.102 requires transplant centers to implement written transplant patient informed consent policies that inform each patient about: (1) The evaluation process; (2) the surgical procedure; (3) alternative treatments; (4) potential medical or psychosocial risks; (5) national and transplant center-specific outcomes; (6) organ donor risk factors that could affect the success of the graft or the health of the patient, including, but not limited to, the donor's history, condition or age of the organs used, or the patient's potential risk of contracting the human immunodeficiency virus and other infectious diseases if the disease cannot be detected in an infected donor; (7) his or her right to refuse transplantation; and (8) the fact that if a transplant is not provided in a Medicare-approved transplant center, it could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid under Medicare Part B.

Section 482.102(b) also requires transplant centers to implement written living donor informed consent policies that inform the prospective living donor of all aspects of, and potential outcomes from, living donation. The centers must ensure that the prospective living donor is fully informed about: (1) The fact that communication between the donor and the transplant center will remain confidential; (2) the evaluation process; (3) the surgical procedure, including post-operative treatment; (4) the availability of alternative treatments for the transplant recipient; (5) the potential medical or psychosocial risk to the donor; (6) the national and transplant center-specific outcomes for recipients; and the national and center-specific outcomes for living donors, as data are available; (7) the possibility that future health problems related to the donation may not be covered by the donor's insurance and that the donor's ability to obtain health, disability, or life insurance may be affected; and (8) the donor's right to opt out of donation at any time during the donation process; and (9) the fact that if a transplant is not provided in a Medicare-approved transplant center, it could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid under Medicare Part B.

We believe that all transplant centers currently have policies regarding informed consent. Although we acknowledge that some centers may need to review and revise their informed consent policies to satisfy the requirements for this section, we believe that the economic impact will be minimal.

Section 482.102(c) requires a transplant center to notify patients placed on the center's waiting list of information about the center that could impact the patient's ability to receive a transplant should an organ become available, and what procedures are in place to ensure the availability of a transplant team. Section 482.102(c)(1) specifically requires a transplant center served by a single transplant surgeon or physician to inform patients placed on the center's waiting list of the potential unavailability of the transplant surgeon or physician and to indicate whether or not the center has a mechanism to provide an alternate transplant surgeon or transplant physician.

In the public comments we received to the proposed rule, one commenter pointed out that complying with this requirement would entail the drafting of a letter by an administrator, approval by the surgeon, searching a database to identify appropriate patients, clerical or support resources to prepare and mail the letters, and the expense associated with actually mailing the letters. The commenter pointed out that this would be an extensive and unrealistic use of resources for short-term unavailability issues, such as the absence of the transplant surgeon.

As discussed earlier in this preamble, this provision does not require that transplant centers inform waiting list patients on an ongoing basis about the short-term unavailability of a transplant surgeon, such as, when a transplant surgeon is on vacation. The provision simply requires that at the time a patient is placed on the waiting list, the patient must be informed about circumstances that could impact the patient's ability to receive a transplant and what procedures the transplant center has in place to address these circumstances. Clearly, this requirement is particularly important when a transplant center is served by a single surgeon. We expect that most transplant centers already provide this information to patients when they are placed on the waiting list. Thus, the economic impact for this requirement is minimal.

Section 482.102(c)(2) requires that, at least 30 days before a transplant center's Medicare approval is terminated, either voluntarily or involuntarily, the center must inform patients on its waiting list of this fact and provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list. The transplant center must also inform Medicare beneficiaries on the center's waiting list that Medicare will no longer pay for transplants performed at the center after the effective date of the center's loss of Medicare approval.

Section 482.102(c)(3) requires that as soon as possible prior to a transplant center's voluntary inactivation, the center must inform patients on its waiting list and, as directed by the Secretary, provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list as soon as possible.

We expect that transplant centers would inform waiting list patients by mail. We estimate that it would require an administrator approximately 30 minutes to draft a letter. A secretary or other support staff person would copy and mail these letters to the individuals on the center's waiting list. Based on our estimate, the economic impact of performing these tasks would be $100.69 for each center.

TOTAL BURDEN HOURS AND TOTAL COST ESTIMATE FOR NOTIFYING PATIENTS ON A CENTER'S WAITING LIST OF A TRANSPLANT CENTER'S LOSS OF MEDICARE APPROVAL

Position	Hourly wage	Hours required	Total cost estimate
Senior Administrator	$ 92.31	.50	$ 46.16
Secretary	21.81	2.50	54.53
Totals	.....	3.00	100.69

All salary information is from the salary.com Web site at *http://hrsalarycenter.salary.com*

In addition, the transplant center would incur costs for paper, envelopes, and postage. We estimate these costs to total $.55 per mailing. On average, each transplant center has 112 patients, so the total cost of mailing the letter to each waiting list patient would be approximately $61.60 (112 patients × $.55 = $61.60).

As discussed in more detail below under § 488.61, we believe that based upon the requirements contained in this final rule, up to two percent of transplant centers or approximately 10 centers may lose their Medicare approved status annually. If 10 centers annually lost their Medicare approved status, either voluntarily or involuntarily, the total cost estimate would be $1,622.90 ($100.69 salary cost estimate + $61.60 materials/postage cost estimate x 10 transplant centers = $1,622.90).

Section 482.104 Condition of Participation: Additional Requirements for Kidney Transplant Centers

Section 482.104(a) requires kidney transplant centers to directly furnish transplantation and other medical and surgical specialty services required for the care of ESRD patients. The centers must have written policies and procedures for ongoing communications with the dialysis patients' local dialysis facilities. Section 482.104(b) states that the kidney transplant centers must also furnish inpatient dialysis services directly or under arrangement. In addition, Section 482.104(c) states that the centers must cooperate with the ESRD network designated for their geographic area, in fulfilling the terms of the Network's current statement of work.

We believe that these requirements constitute standard practice for transplant centers. Thus, the activities required to comply with this section constitute a minimal economic impact.

Section 488.61 Special Procedures for Approval and Re-Approval of Organ Transplant Centers

Section 488.61(a) requires transplant centers that are not Medicare-approved as of June 28, 2007 to submit a request to CMS for Medicare approval. Section 488.61(b) requires transplant centers, including kidney transplant centers, that are Medicare approved as of June 28, 2007 to submit a request for Medicare approval no later than December 26, 2007. The process for making the request for Medicare approval is the same for both types of transplant centers. (See § 488.61(b)(1).) The request for Medicare approval must be signed by a person authorized to represent the center (for example, a chief executive officer). The request must include the hospital's Medicare provider identification (I.D.) number; the name(s) of the designated primary transplant surgeon and primary transplant physician; and a statement from the OPTN that the center has complied with all data submission requirements.

In the proposed rule, we estimated that each hospital would spend approximately 15 minutes to prepare and submit the request for Medicare approval to CMS. We did note that a hospital may have multiple transplant centers and, therefore, could be submitting more than one request for approval.

We received public comments on the proposed rule that said we had underestimated the time required for a transplant center to apply for Medicare approval. One commenter emphasized that transplant centers regard applying for Medicare approval very seriously. The commenter also indicated that the preparation, approval, and submission of the request for Medicare approval could take days at many large institutions. After further analysis of the tasks and the personnel that would be involved in applying for Medicare approval, we agree with the commenters that 15 minutes significantly underestimates the time required to prepare the request, obtain the required center approval(s), and submit the request for Medicare approval to CMS. However, we disagree with the commenter that said it could take ''days'' to accomplish all of the required tasks. Our analysis of the total cost estimate is discussed in detail below.

We believe that accomplishing all of the tasks necessary for complying with Section 488.61(a) would involve the transplant program's medical director, an administrator, a transplant coordinator, and appropriate support/administrative staff. We estimate that it would take these individuals approximately the same amount of time as it would take the transplant center to notify CMS of a significant change in their program or approximately 2 burden hours.

TOTAL ANNUAL BURDEN HOURS AND TOTAL ANNUAL COST FOR A TRANSPLANT CENTER TO APPLY FOR MEDICARE APPROVAL

Position	Hourly wage	Hours required	Total cost estimate
Medical Director	$116.60	.50	$58.30
Senior Administrator	92.31	.50	46.16
Transplant Coordinator	43.87	.75	32.90
Secretary	$21.81	.25	$5.45
Totals	.....	2.00	142.81

All salary information is from the salary.com Web site at *http://hrsalarycenter.salary.com*

This final rule requires all currently-approved transplant centers that want to continue to provide services to Medicare beneficiaries to apply for initial approval. There are currently approximately 504 Medicare-approved transplant centers. We believe that all 504 transplant centers will submit letters requesting initial approval under the requirements of this final rule. In addition, based on our experience, we believe that approximately 10 new centers a year may apply for Medicare approval. Thus, we anticipate that 514 transplant centers will apply for Medicare in the first year following the effective date of this final rule.

For the first year after the effective date of this final rule, the total cost estimate would be $73,404.34 (514 transplant centers × $142.81 = $73,404.34). For subsequent years, we anticipate that about 10 transplant centers will request initial Medicare approval. For those subsequent years, the total cost estimate would be $1,428.10 (10 transplant centers × $142.81 = $1,428.10).

Section 488.61(d) allows transplant centers that have lost their Medicare approval to seek re-entry into the Medicare program at any time. If a center chooses to seek Medicare approval after losing it, the center must: (1) request initial approval using the procedures at § 488.61(a); (2) be in compliance with §§ 482.72 through 482.104, except for § 482.82 (Re-approval Requirements), at the time of the request for Medicare approval; and (3) submit a report to CMS documenting any changes or corrective action taken by the center as a result of the loss of its Medicare approval status.

A transplant center would utilize resources to prepare and submit a request for approval to CMS pursuant to § 488.61(a) and to prepare and submit a report to CMS documenting any changes or corrective action taken by the center as a result of the loss of its Medicare approval status. After further analysis of the tasks that would be involved and the personnel that would be needed, developing and submitting the requests and the report would involve the transplant program's medical director, an administrator, a transplant coordinator, and appropriate support or administrative staff. We also believe that it will require more time to request re-entry into the Medicare program due to the development of the report documenting any changes or corrective action taken by the center as a result of the loss of its Medicare approval status.

During 2005 and 2006, only six centers voluntarily terminated their Medicare approval. Transplant centers have rarely had their Medicare approval status revoked involuntarily. However, this final rule has outcome requirements, clinical experience requirements, and process requirements that transplant centers must generally meet to obtain initial Medicare approval and to retain their approval. Considering these requirements, we anticipate that more centers may voluntarily terminate their Medicare approval status in order to give themselves time to correct any problems they may have in meeting these requirements. In addition, it may become more common for transplant centers to be involuntarily terminated from the Medicare program. Therefore, we estimate that, in any given year, up to two percent, or approximately 10, of the currently 504 Medicare-approved centers may lose their status annually and later seek to re-enter the program.

Based on the above, we estimate that a transplant center complying with the requirements to apply for initial approval would incur a total cost of $329.50. In any given year, we anticipate that as many as 10 centers may seek to re-enter the Medicare program. For these 10 centers, the total cost estimate would be $ 3,295.00 ($329.50 per center to re-apply × 10 centers = $ 3,295.00).

TOTAL ANNUAL BURDEN HOURS AND TOTAL ANNUAL COST FOR TRANSPLANT CENTERS SEEKING RE-ENTRY INTO THE MEDICARE PROGRAM AFTER LOSS OF MEDICARE APPROVAL

Position	Hourly wage	Hours required	Total cost estimate
Medical Director	$116.60	1.00	$116.60
Senior Administrator	92.31	1.00	92.31
Transplant Coordinator	43.87	2.50	109.68
Secretary	21.81	.50	10.91
Totals	.....	5.00	329.50

All salary information is from the salary.com Web site at *http://hrsalarycenter.salary.com*

Thus, the estimated total economic impact for this section in the first year after this final rule becomes effective is $73,404.34 (514 transplant centers × $142.81 = $73,404.34). For subsequent years, the estimated annual total economic impact is $4,723.10 ($1,428.10 + $3,295.00 = $4,723.10).

Our estimate of the first-year economic impact on transplant centers to meet the requirements in this final rule are as follows:

- $215,928 for notification to CMS of significant changes to the center's transplant program.
- $95,882 annually for kidney transplant centers to notify dialysis facilities' of their patients' waiting list status.
- $311,172 to revise agreements with OPOs.
- $18,474,112 to develop and implement a QAPI program.
- $9,248,136 to provide a living donor advocate in those centers that perform living donor transplantations.
- $1,622 for centers that have lost their Medicare approval status to notify the patients on their waiting list.
- $73,404 in the first year of implementation of this final rule to apply for Medicare approval.

Summary of Direct Cost

The overall first year economic impact of implementing the requirements in this final rule will be approximately $28,420,256, and the first year cost to each of the transplant centers will be an average of about $56,389 per transplant center. This figure includes the total compensation for all of the staff hours that were calculated.

Benefits and Effects of This Final Rule

The primary economic benefit of this final rule lies with its potential to improve Medicare-approved transplant centers' effectiveness and efficiency and thus reduce the number of patient deaths and graft failures for patients who receive transplants at Medicare-approved facilities. We believe that implementing the requirements in this final rule will result in a decrease in patient deaths and graft failures.

However, it is difficult to estimate the percentage of that decrease. For some transplant centers, most of the requirements in this final rule are already standard practice. Other centers will need to make only minor improvements to their current processes and practices. And, some transplant centers will need to make substantial modifications to their processes and practices to be in compliance. In addition, while some requirements will probably have only a minor, if any, effect on patient outcomes, there are certain requirements that we believe have the potential to substantially improve patient outcomes. For example, § 482.72(a) requires transplant centers to submit to the OPTN at least 95 percent of the required data on all transplants it has performed no later than 90 days after the due date established by the OPTN. Since this is already a requirement of the OPTN and the hospitals in which transplant centers are located must already belong to the OPTN, we do not anticipate that this requirement in the final rule will have any effect on patient outcomes. However, other requirements could have a substantial effect. Section 482.96 requires that transplant centers must develop, implement, and maintain a written, comprehensive, data-driven quality assessment and performance improvement (QAPI) program designed to monitor and evaluate performance of all transplantation services. These types of QAPI programs have the potential to substantially improve patient outcomes. Centers that do not have such QAPI programs currently could experience substantial improvements in their patient outcomes. However, since some centers are already complying with the QAPI requirement, as well as the other requirements in the final rule, we do not believe that the increase in improvement for all transplant centers will be substantial. Due to the current diversity in processes and procedures existing in transplant centers, we cannot calculate any percentage of decrease in patient deaths or graft failures to any degree of reasonable certainty. Thus, we will not be able to quantify the social benefits we believe will result from implementation of this final rule.

The social benefits from the implementation of this regulation will result from both the lives saved and the decrease in graft failures. Organ failure is usually fatal within a short period of time. Patients with ESRD are an exception. Some ESRD patients can survive for many years on dialysis and many of those patients can do quite well. However, dialysis is quite demanding and requires a substantial commitment on the part of these patients and their families. Therefore, kidney transplantation offers these patients a substantially increased quality of life. In addition, graft failures for very seriously ill patients often require re-transplantation for the patient to survive for more than a short length of time. And, considering the significant shortage of transplantable organs, it is crucial for transplant centers to operate efficiently and provide the best quality of care to transplant recipients to optimize the use of the transplantable organs that are available.

In addition to a decrease in patient deaths and graft failures, many of the requirements in this regulation should contribute to a higher quality of care for both transplant recipients and living donors. This increase in the quality of care will result in substantial social benefits. For example, the requirements for informed consent, donor management, a living donor advocate or living donor advocate team, and psychosocial evaluations of both potential transplant recipients and living donors should all lead to an improvement in the quality of care received by both transplant recipients and living donors. Based upon the above, we believe that the social benefits from the implementation of this final rule include:

- Increase in years of life gained.
- Improvements in quality of life, particularly for chronic kidney disease patients who can terminate dialysis.
- Resumption of work/volunteerism/productivity for some patients.
- An increase in the number of taxpayers (patients who return to work).
- An increase in family stability due to the life saved and improved health of a family member.
- An increase in access to dialysis as more patients receive kidney transplants.
- An increase in the number of patients who are transplanted due to the reduction in patients who need to be re-transplanted due to graft failures.
- Improved quality of care for both potential and actual transplant recipients and living donors.

Effects on the Medicare Program

In addition to the social benefits discussed above, we can estimate a monetary benefit from a reduction in the number of kidney graft failures, which forces kidney transplant patients to return to dialysis for treatment. Medicare pays for kidney dialysis for the vast majority of dialysis patients in the United States.

In 2003 (the most recent year for which complete data are available), there were 15,722 kidney (deceased or living donor) and kidney-pancreas transplants. Of the approximately 15,722 patients who received these transplants, 1-year graft survival data show that 1288 (less than 10 percent) of kidney grafts failed. We do not have data to show how many of the transplants were performed at Medicare-approved facilities, but since all or nearly all kidney transplant centers are Medicare approved, we will assume that all 2003 kidney and kidney-pancreas transplants were performed at Medicare-approved transplant centers. As stated above, we believe that the improvement in the number of graft failures will be modest. We estimate that the improvement could be from 1 to 3 percent. A 1 to 3 percent decrease in kidney graft failures would result in approximately 13 to 39 fewer graft failures in the first year after implementation of this regulation. Based on the median decrease of 2 percent, we can estimate that there could be as many as 26 fewer kidney graft failures.

The 2003 average per person per year primary payer cost for dialysis patients was $63,723, while the cost for end-stage renal disease patients with a functioning kidney graft was $15,357 (United States Renal Data System (USRDS): 2005 Annual Data Report: Atlas of End-Stage Renal Disease in the United States pages 674 and 680). Therefore, net health care cost savings would be $48,366 annually per patient and the cost savings for 26 patients would be $1,257,516 (26 patients × $48,366 cost savings per patient = $1,257,516).

It is important to note that re-transplantation of a kidney patient who experiences graft failure prevents a patient on the kidney waiting list from receiving a kidney and, thus, ending dialysis treatment. It is also important to note that while fewer graft failures will result in more patients receiving a first transplant (rather than a re-transplant), we estimate that the number of organs available for transplantation will remain the same. Thus, we do not anticipate that Medicare will face increased costs because the number of transplants should remain approximately the same.

We expect that the procedures for approval and re-approval contained in this final rule will have some economic impact on the Medicare program because CMS will need to survey all 504 transplant centers that are currently approved by Medicare if they wish to continue to provide services to Medicare beneficiaries. Furthermore,

under this final rule, all transplant centers must be re-approved every 3 years, and some centers will be surveyed as part of our re-approval process. Thus, this final rule is likely to increase survey costs.

Nevertheless, to the extent possible, we will minimize costs by prioritizing surveys based on transplant centers performance on the outcome requirements and by conducting surveys in the most efficient way possible. For example, all transplant centers located in the same hospital will be surveyed at the same time.

In addition, since Medicare reimbursement rates are either directly or indirectly influenced by a hospital's costs, we may eventually increase Medicare reimbursement to transplant centers to cover some of the costs of their extra responsibilities. Medicare pays hospitals on a cost basis for certain ''organ acquisition costs''. Costs related to the requirement to have a donor advocate or donor advocate team are organ acquisition costs.

Medicare generally reimburses hospitals for organ transplant costs for beneficiaries using diagnosis related groups (DRGs) in all States, except for Maryland. DRG payments are periodically re-weighted in a budget neutral fashion to increase payments for procedures that have costs that are growing at a faster rate than most other procedures. Therefore, it is possible that DRGs for organ transplants will increase and therefore offset some of the hospitals' costs under the various transplant DRGs.

Conclusion

We believe that the requirements in this final rule will ensure that the organ transplants made available to patients are provided in a safe and effective manner. We also believe that this final rule will ensure that living donors receive the guidance and care that they deserve. We estimate that the first year cost of implementing this final rule is $28,420,256. The cost of implementation in subsequent years is estimated to be $9,566,291 annually.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 482

Grant programs-health, Hospitals, Medicare, reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health Facilities, Health professions, Medicare, reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart U—Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

■ 1. The authority citation for part 405, Subpart U continues to read as follows:

Authority: Secs. 1102, 1138, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1320b–8, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr), unless otherwise noted.

§ 405.2102 [Amended]

■ 2. Section 405.2102 is amended by—

■ A. Removing the definitions for ''histocompatibility testing'' and ''organ procurement''.

■ B. Amending the definition of ''ESRD facility'' by removing paragraph (a) and by re-designating paragraphs (b) through (e) as paragraphs (a) through (d).

■ C. Amending the definition of ''ESRD service'' by removing paragraph (a) and by re-designating paragraphs (b) and (c) as paragraphs (a) and (b).

■ D. Amending the definition of ''Qualified personnel'' by removing paragraph (g).

§§ 405.2120 through 405.2124 [Removed]

■ 3. Sections 405.2120 through 405.2124 are removed.

§ 405.2130 [Removed]

■ 4. Section 405.2130 is removed.

§§ 405.2170 and 405.2171 [Removed]

■ 5. Section 405.2170 and 405.2171 are removed.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 6. The authority citation for part 482 is revised to read as follows:

Authority: Secs. 1102, 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

■ 7. Part 482 is amended by revising subpart E to read as follows:

Subpart E—Requirements for Specialty Hospitals

Sec.

Subpart E—Requirements for Specialty Hospitals

§ 482.68 Special requirements for transplant centers.

A transplant center located within a hospital that has a Medicare provider agreement must meet the conditions of participation specified in § 482.72 through § 482.104 in order to be granted approval from CMS to provide transplant services.

(a) Unless specified otherwise, the conditions of participation at § 482.72 through § 482.104 apply to heart, heart-lung, intestine, kidney, liver, lung, and pancreas centers.

(b) In addition to meeting the conditions of participation specified in § 482.72 through § 482.104, a transplant center must also meet the conditions of participation specified in § 482.1 through § 482.57.

§ 482.70 Definitions.

As used in this subpart, the following definitions apply:

Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof. As applied to transplant centers, examples of adverse events include (but are not limited to) serious medical complications or death caused by living donation; unintentional transplantation of organs of mismatched blood types; transplantation of organs to unintended recipients; and unintended transmission of infectious disease to a recipient.

End-Stage Renal Disease (ESRD) means that stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

ESRD Network means all Medicare-approved ESRD facilities in a designated geographic area specified by CMS.

Heart-Lung transplant center means a transplant center that is located in a hospital with an existing Medicare-approved heart transplant center and an existing Medicare-approved lung center that performs combined heart-lung transplants.

Intestine transplant center means a Medicare-approved liver transplant center that performs intestine transplants, combined liver-intestine transplants, or multivisceral transplants.

Network organization means the administrative governing body to the network and liaison to the Federal government.

Pancreas transplant center means a Medicare-approved kidney transplant center that performs pancreas transplants alone or subsequent to a kidney transplant as well as kidney-pancreas transplants.

Transplant center means an organ-specific transplant program (as defined in this rule) within a transplant hospital (for example, a hospital's lung transplant program may also be referred to as the hospital's lung transplant center).

Transplant hospital means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

Transplant program means a component within a transplant hospital (as defined in this rule) that provides transplantation of a particular type of organ.

General Requirements for Transplant Centers

§ 482.72 Condition of participation: OPTN membership.

A transplant center must be located in a transplant hospital that is a member of and abides by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274). The term ''rules and requirements of the OPTN'' means those rules and requirements approved by the Secretary pursuant to § 121.4 of this title. No hospital that provides transplantation services shall be deemed to be out of compliance with section 1138(a)(1)(B) of the Act or this section unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the transplant hospital from the OPTN and also has notified the transplant hospital in writing.

§ 482.74 Condition of participation: Notification to CMS.

(a) A transplant center must notify CMS immediately of any significant changes related to the center's transplant program or changes that could affect its compliance with the conditions of participation. Instances in which CMS should receive information for follow up, as appropriate, include, but are not limited to:

(1) Change in key staff members of the transplant team, such as a change in the individual the transplant center designated to the OPTN as the center's ''primary transplant surgeon'' or ''primary transplant physician;'

(2) A decrease in the center's number of transplants or survival rates that could result in the center being out of compliance with § 482.82;

(3) Termination of an agreement between the hospital in which the transplant center is located and an OPO for the recovery and receipt of organs as required by section 482.100; and

(4) Inactivation of the transplant center.

(b) Upon receiving notification of significant changes, CMS will follow up with the transplant center as appropriate, including (but not limited to):

(1) Requesting additional information;

(2) Analyzing the information; or

(3) Conducting an on-site review.

§ 482.76 Condition of participation: Pediatric Transplants.

A transplant center that seeks Medicare approval to provide transplantation services to pediatric patients must submit to CMS a request specifically for Medicare approval to perform pediatric transplants using the procedures described at § 488.61 of this chapter.

(a) Except as specified in paragraph (d) of this section, a center requesting Medicare approval to perform pediatric transplants must meet all the conditions of participation at § 482.72 through § 482.74 and § 482.80 through § 482.104 with respect to its pediatric patients.

(b) A center that performs 50 percent or more of its transplants in a 12-month period on adult patients must be approved to perform adult transplants in order to be approved to perform pediatric transplants.

(1) Loss of Medicare approval to perform adult transplants, whether voluntary or involuntary, will result in loss of the center's approval to perform pediatric transplants.

(2) Loss of Medicare approval to perform pediatric transplants, whether voluntary or involuntary, may trigger a review of the center's Medicare approval to perform adult transplants.

(c) A center that performs 50 percent or more of its transplants in a 12-month period on pediatric patients must be approved to perform pediatric transplants in order to be approved to perform adult transplants.

(1) Loss of Medicare approval to perform pediatric transplants, whether voluntary or involuntary, will result in loss of the center's approval to perform adult transplants.

(2) Loss of Medicare approval to perform adult transplants, whether voluntary or involuntary, may trigger a review of the center's Medicare approval to perform pediatric transplants.

(3) A center that performs 50 percent or more of its transplants on pediatric patients in a 12-month period is not required to meet the clinical experience requirements prior to its request for approval as a pediatric transplant center.

(d) Instead of meeting all conditions of participation at § 482.72 through § 482.74 and § 482.80 through § 482.104, a heart transplant center that wishes to provide transplantation services to pediatric heart patients may be approved to perform pediatric heart transplants by meeting the Omnibus Budget Reconciliation Act of 1987 criteria in section 4009(b) (Pub. L. 100–203), as follows:

(1) The center's pediatric transplant program must be operated jointly by the hospital and another facility that is Medicare-approved;

(2) The unified program shares the same transplant surgeons and quality

improvement program (including oversight committee, patient protocol, and patient selection criteria); and

(3) The center demonstrates to the satisfaction of the Secretary that it is able to provide the specialized facilities, services, and personnel that are required by pediatric heart transplant patients.

Transplant Center Data Submission, Clinical Experience, and Outcome Requirements

§ 482.80 Condition of participation: Data submission, clinical experience, and outcome requirements for initial approval of transplant centers.

Except as specified in paragraph (d) of this section, and § 488.61 of this chapter, transplant centers must meet all data submission, clinical experience, and outcome requirements to be granted initial approval by CMS.

(a) *Standard: Data submission.* No later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of required data on all transplants (deceased and living donor) it has performed. Required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration and follow-up, and living donor registration and follow-up.

(b) *Standard: Clinical experience.* To be considered for initial approval, an organ-specific transplant center must generally perform 10 transplants over a 12-month period.

(c) *Standard: Outcome requirements.* CMS will review outcomes for all transplants performed at a center, including outcomes for living donor transplants, if applicable. Except for lung transplants, CMS will review adult and pediatric outcomes separately when a center requests Medicare approval to perform both adult and pediatric transplants.

(1) CMS will compare each transplant center's observed number of patient deaths and graft failures 1-year post-transplant to the center's expected number of patient deaths and graft failures 1-year post-transplant using the data contained in the most recent Scientific Registry of Transplant Recipients (SRTR) center-specific report.

(2) The required number of transplants must have been performed during the time frame reported in the most recent SRTR center-specific report.

(3) CMS will not consider a center's patient and graft survival rates to be acceptable if:

(i) A center's observed patient survival rate or observed graft survival rate is lower than its expected patient survival rate or expected graft survival rate; and

(ii) All three of the following thresholds are crossed over:

(A) The one-sided p-value is less than 0.05,

(B) The number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and

(C) The number of observed events divided by the number of expected events is greater than 1.5.

(d) *Exceptions.* (1) A heart-lung transplant center is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for heart-lung transplants performed at the center.

(2) An intestine transplant center is not required to comply with the outcome performance requirements in paragraph (c) of this section for intestine, combined liver-intestine or multivisceral transplants performed at the center.

(3) A pancreas transplant center is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for pancreas transplants performed at the center.

(4) A center that is requesting initial Medicare approval to perform pediatric transplants is not required to comply with the clinical experience requirements in paragraph (b) of this section prior to its request for approval as a pediatric transplant center.

(5) A kidney transplant center that is not Medicare-approved on the effective date of this rule is required to perform at least 3 transplants over a 12-month period prior to its request for initial approval.

§ 482.82 Condition of participation: Data submission, clinical experience, and outcome requirements for re-approval of transplant centers.

Except as specified in paragraph (d) of this section, and § 488.61 of this chapter, transplant centers must meet all data submission, clinical experience, and outcome requirements in order to be re-approved.

(a) *Standard: Data submission.* No later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of the required data submissions on all transplants (deceased and living donor) it has performed over the 3-year approval period. Required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration and follow-up, and living donor registration and follow-up.

(b) *Standard: Clinical experience.* To be considered for re-approval, an organ-specific transplant center must generally perform an average of 10 transplants per year during the re-approval period.

(c) *Standard: Outcome requirements.* CMS will review outcomes for all transplants performed at a center, including outcomes for living donor transplants if applicable. Except for lung transplants, CMS will review adult and pediatric outcomes separately when a center requests Medicare approval to perform both adult and pediatric transplants.

(1) CMS will compare each transplant center's observed number of patient deaths and graft failures 1-year post-transplant to the center's expected number of patient deaths and graft failures 1-year post-transplant using data contained in the most recent SRTR center-specific report.

(2) The required number of transplants must have been performed during the time frame reported in the most recent SRTR center-specific report.

(3) CMS will not consider a center's patient and graft survival rates to be acceptable if:

(i) A center's observed patient survival rate or observed graft survival rate is lower than its expected patient survival rate and graft survival rate; and

(ii) All three of the following thresholds are crossed over:

(A) The one-sided p-value is less than 0.05,

(B) The number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and

(C) The number of observed events divided by the number of expected events is greater than 1.5.

(d) *Exceptions.* (1) A heart-lung transplant center is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for heart-lung transplants performed at the center.

(2) An intestine transplant center is not required to comply with the outcome requirements in paragraph (c) of this section for intestine, combined liver-intestine, and multivisceral transplants performed at the center.

(3) A pancreas transplant center is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome

requirements in paragraph (c) of this section for pancreas transplants performed at the center.

(4) A center that is approved to perform pediatric transplants is not required to comply with the clinical experience requirements in paragraph (b) of this section to be re-approved.

Transplant Center Process Requirements

§ 482.90 Condition of participation: Patient and living donor selection.

The transplant center must use written patient selection criteria in determining a patient's suitability for placement on the waiting list or a patient's suitability for transplantation. If a center performs living donor transplants, the center also must use written donor selection criteria in determining the suitability of candidates for donation.

(a) *Standard: Patient selection.* Patient selection criteria must ensure fair and non-discriminatory distribution of organs.

(1) Prior to placement on the center's waiting list, a prospective transplant candidate must receive a psychosocial evaluation, if possible.

(2) Before a transplant center places a transplant candidate on its waiting list, the candidate's medical record must contain documentation that the candidate's blood type has been determined.

(3) When a patient is placed on a center's waiting list or is selected to receive a transplant, the center must document in the patient's medical record the patient selection criteria used.

(4) A transplant center must provide a copy of its patient selection criteria to a transplant patient, or a dialysis facility, as requested by a patient or a dialysis facility.

(b) *Standard: Living donor selection.* The living donor selection criteria must be consistent with the general principles of medical ethics. Transplant centers must:

(1) Ensure that a prospective living donor receives a medical and psychosocial evaluation prior to donation,

(2) Document in the living donor's medical records the living donor's suitability for donation, and

(3) Document that the living donor has given informed consent, as required under § 482.102.

§ 482.92 Condition of participation: Organ recovery and receipt.

Transplant centers must have written protocols for validation of donor-recipient blood type and other vital data for the deceased organ recovery, organ receipt, and living donor organ transplantation processes. The transplanting surgeon at the transplant center is responsible for ensuring the medical suitability of donor organs for transplantation into the intended recipient.

(a) *Standard: Organ recovery.* When the identity of an intended transplant recipient is known and the transplant center sends a team to recover the organ(s), the transplant center's recovery team must review and compare the donor data with the recipient blood type and other vital data before organ recovery takes place.

(b) *Standard: Organ receipt.* After an organ arrives at a transplant center, prior to transplantation, the transplanting surgeon and another licensed health care professional must verify that the donor's blood type and other vital data are compatible with transplantation of the intended recipient

(c) *Standard: Living donor transplantation.* If a center performs living donor transplants, the transplanting surgeon and another licensed health care professional at the center must verify that the living donor's blood type and other vital data are compatible with transplantation of the intended recipient immediately before the removal of the donor organ(s) and, if applicable, prior to the removal of the recipient's organ(s).

§ 482.94 Condition of participation: Patient and living donor management.

Transplant centers must have written patient management policies for the transplant and discharge phases of transplantation. If a transplant center performs living donor transplants, the center also must have written donor management policies for the donor evaluation, donation, and discharge phases of living organ donation.

(a) *Standard: Patient and living donor care.* The transplant center's patient and donor management policies must ensure that:

(1) Each transplant patient is under the care of a multidisciplinary patient care team coordinated by a physician throughout the transplant and discharge phases of transplantation; and

(2) If a center performs living donor transplants, each living donor is under the care of a multidisciplinary patient care team coordinated by a physician throughout the donor evaluation, donation, and discharge phases of donation.

(b) *Standard: Waiting list management.* Transplant centers must keep their waiting lists up to date on an ongoing basis, including:

(1) Updating of waiting list patients' clinical information;

(2) Removing patients from the center's waiting list if a patient receives a transplant or dies, or if there is any other reason the patient should no longer be on a center's waiting list; and

(3) Notifying the OPTN no later than 24 hours after a patient's removal from the center's waiting list.

(c) *Standard: Patient records.* Transplant centers must maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a center's waiting list and who is admitted for organ transplantation.

(1) For each patient who receives an evaluation for placement on a center's waiting list, the center must document in the patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) has been informed of his or her transplant status, including notification of:

(i) The patient's placement on the center's waiting list;

(ii) The center's decision not to place the patient on its waiting list; or

(iii) The center's inability to make a determination regarding the patient's placement on its waiting list because further clinical testing or documentation is needed.

(2) If a patient on the waiting list is removed from the waiting list for any reason other than death or transplantation, the transplant center must document in the patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) was notified no later than 10 days after the date the patient was removed from the waiting list.

(3) In the case of patients admitted for organ transplants, transplant centers must maintain written records of:

(i) Multidisciplinary patient care planning during the transplant period; and

(ii) Multidisciplinary discharge planning for post-transplant care.

(d) *Standard: Social services.* The transplant center must make social services available, furnished by qualified social workers, to transplant patients, living donors, and their families. A qualified social worker is an individual who meets licensing requirements in the State in which he or she practices; and

(1) Completed a course of study with specialization in clinical practice and holds a master's degree from a graduate school of social work accredited by the Council on Social Work Education; or

(2) Is working as a social worker in a transplant center as of the effective date of this final rule and has served for at

least 2 years as a social worker, 1 year of which was in a transplantation program, and has established a consultative relationship with a social worker who is qualified under (d)(1) of this paragraph.

(e) *Standard: Nutritional services.* Transplant centers must make nutritional assessments and diet counseling services, furnished by a qualified dietitian, available to all transplant patients and living donors. A qualified dietitian is an individual who meets practice requirements in the State in which he or she practices and is a registered dietitian with the Commission on Dietetic Registration.

§ 482.96 Condition of participation: Quality assessment and performance improvement (QAPI).

Transplant centers must develop, implement, and maintain a written, comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all transplantation services, including services provided under contract or arrangement.

(a) *Standard: Components of a QAPI program.* The transplant center's QAPI program must use objective measures to evaluate the center's performance with regard to transplantation activities and outcomes. Outcome measures may include, but are not limited to, patient and donor selection criteria, accuracy of the waiting list in accordance with the OPTN waiting list requirements, accuracy of donor and recipient matching, patient and donor management, techniques for organ recovery, consent practices, patient education, patient satisfaction, and patient rights. The transplant center must take actions that result in performance improvements and track performance to ensure that improvements are sustained.

(b) *Standard: Adverse events.* A transplant center must establish and implement written policies to address and document adverse events that occur during any phase of an organ transplantation case.

(1) The policies must address, at a minimum, the process for the identification, reporting, analysis, and prevention of adverse events.

(2) The transplant center must conduct a thorough analysis of and document any adverse event and must utilize the analysis to effect changes in the transplant center's policies and practices to prevent repeat incidents.

§ 482.98 Condition of participation: Human resources.

The transplant center must ensure that all individuals who provide services and/or supervise services at the center, including individuals furnishing services under contract or arrangement, are qualified to provide or supervise such services.

(a) *Standard: Director of a transplant center.* The transplant center must be under the general supervision of a qualified transplant surgeon or a qualified physician-director. The director of a transplant center need not serve full-time and may also serve as a center's primary transplant surgeon or transplant physician in accordance with § 482.98(b). The director is responsible for planning, organizing, conducting, and directing the transplant center and must devote sufficient time to carry out these responsibilities, which include but are not limited to the following:

(1) Coordinating with the hospital in which the transplant center is located to ensure adequate training of nursing staff and clinical transplant coordinators in the care of transplant patients and living donors.

(2) Ensuring that tissue typing and organ procurement services are available.

(3) Ensuring that transplantation surgery is performed by, or under the direct supervision of, a qualified transplant surgeon in accordance with § 482.98(b).

(b) *Standard: Transplant surgeon and physician.* The transplant center must identify to the OPTN a primary transplant surgeon and a transplant physician with the appropriate training and experience to provide transplantation services, who are immediately available to provide transplantation services when an organ is offered for transplantation.

(1) The transplant surgeon is responsible for providing surgical services related to transplantation.

(2) The transplant physician is responsible for providing and coordinating transplantation care.

(c) *Standard: Clinical transplant coordinator.* The transplant center must have a clinical transplant coordinator to ensure the continuity of care of patients and living donors during the pre-transplant, transplant, and discharge phases of transplantation and the donor evaluation, donation, and discharge phases of donation. The clinical transplant coordinator must be a registered nurse or clinician licensed by the State in which the clinical transplant coordinator practices, who has experience and knowledge of transplantation and living donation issues. The clinical transplant coordinator's responsibilities must include, but are not limited to, the following:

(1) Ensuring the coordination of the clinical aspects of transplant patient and living donor care; and

(2) Acting as a liaison between a kidney transplant center and dialysis facilities, as applicable.

(d) *Standard: Independent living donor advocate or living donor advocate team.* The transplant center that performs living donor transplantation must identify either an independent living donor advocate or an independent living donor advocate team to ensure protection of the rights of living donors and prospective living donors.

(1) The living donor advocate or living donor advocate team must not be involved in transplantation activities on a routine basis.

(2) The independent living donor advocate or living donor advocate team must demonstrate:

(i) Knowledge of living organ donation, transplantation, medical ethics, and informed consent; and

(ii) Understanding of the potential impact of family and other external pressures on the prospective living donor's decision whether to donate and the ability to discuss these issues with the donor.

(3) The independent living donor advocate or living donor advocate team is responsible for:

(i) Representing and advising the donor;

(ii) Protecting and promoting the interests of the donor; and

(iii) Respecting the donor's decision and ensuring that the donor's decision is informed and free from coercion.

(e) *Standard: Transplant team.* The transplant center must identify a multidisciplinary transplant team and describe the responsibilities of each member of the team. The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology.

(f) *Standard: Resource commitment.* The transplant center must demonstrate availability of expertise in internal medicine, surgery, anesthesiology, immunology, infectious disease control, pathology, radiology, blood banking, and patient education as related to the provision of transplantation services.

§ 482.100 Condition of participation: Organ procurement.

The transplant center must ensure that the hospital in which it operates has a written agreement for the receipt of organs with an OPO designated by the Secretary that identifies specific

responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation.

§ 482.102 Condition of participation: Patient and living donor rights.

In addition to meeting the condition of participation ''Patients rights'' requirements at § 482.13, the transplant center must protect and promote each transplant patient's and living donor's rights.

(a) *Standard: Informed consent for transplant patients.* Transplant centers must implement written transplant patient informed consent policies that inform each patient of:

(1) The evaluation process;

(2) The surgical procedure;

(3) Alternative treatments;

(4) Potential medical or psychosocial risks;

(5) National and transplant center-specific outcomes, from the most recent SRTR center-specific report, including (but not limited to) the transplant center's observed and expected 1-year patient and graft survival, national 1-year patient and graft survival, and notification about all Medicare outcome requirements not being met by the transplant center;

(6) Organ donor risk factors that could affect the success of the graft or the health of the patient, including, but not limited to, the donor's history, condition or age of the organs used, or the patient's potential risk of contracting the human immunodeficiency virus and other infectious diseases if the disease cannot be detected in an infected donor;

(7) His or her right to refuse transplantation; and

(8) The fact that if his or her transplant is not provided in a Medicare-approved transplant center it could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid for under Medicare Part B.

(b) *Standard: Informed consent for living donors.* Transplant centers must implement written living donor informed consent policies that inform the prospective living donor of all aspects of, and potential outcomes from, living donation. Transplant centers must ensure that the prospective living donor is fully informed about the following:

(1) The fact that communication between the donor and the transplant center will remain confidential, in accordance with the requirements at 45 CFR parts 160 and 164.

(2) The evaluation process;

(3) The surgical procedure, including post-operative treatment;

(4) The availability of alternative treatments for the transplant recipient;

(5) The potential medical or psychosocial risks to the donor;

(6) The national and transplant center-specific outcomes for recipients, and the national and center-specific outcomes for living donors, as data are available;

(7) The possibility that future health problems related to the donation may not be covered by the donor's insurance and that the donor's ability to obtain health, disability, or life insurance may be affected;

(8) The donor's right to opt out of donation at any time during the donation process; and

(9) The fact that if a transplant is not provided in a Medicare-approved transplant center it could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid for under Medicare Part B.

(c) *Standard: Notification to patients.* Transplant centers must notify patients placed on the center's waiting list of information about the center that could impact the patient's ability to receive a transplant should an organ become available, and what procedures are in place to ensure the availability of a transplant team.

(1) A transplant center served by a single transplant surgeon or physician must inform patients placed on the center's waiting list of:

(i) The potential unavailability of the transplant surgeon or physician; and

(ii) Whether the center has a mechanism to provide an alternate transplant surgeon or transplant physician.

(2) At least 30 days before a center's Medicare approval is terminated, whether voluntarily or involuntarily, the center must:

(i) Inform patients on the center's waiting list and provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list; and

(ii) Inform Medicare beneficiaries on the center's waiting list that Medicare will no longer pay for transplants performed at the center after the effective date of the center's termination of approval.

(3) As soon as possible prior to a transplant center's voluntary inactivation, the center must inform patients on the center's waiting list and, as directed by the Secretary, provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list.

§ 482.104 Condition of participation: Additional requirements for kidney transplant centers.

(a) *Standard: End stage renal disease (ESRD) services.* Kidney transplant centers must directly furnish transplantation and other medical and surgical specialty services required for the care of ESRD patients. A kidney transplant center must have written policies and procedures for ongoing communications with dialysis patients' local dialysis facilities.

(b) *Standard: Dialysis services.* Kidney transplant centers must furnish inpatient dialysis services directly or under arrangement.

(c) *Standard: Participation in network activities.* Kidney transplant centers must cooperate with the ESRD Network designated for their geographic area, in fulfilling the terms of the Network's current statement of work.

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

Subpart A—General Provisions

■ 8. The authority citation for part 488 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh) unless otherwise noted).

§ 488.6 [Amended]

■ 9. Section 488.6(a) is amended by adding ''transplant centers, except for kidney transplant centers;'' after ''psychiatric hospitals;'' but before ''SNFs.''

Subpart B—Special Requirements

■ 10. Section 488.61 is added to subpart B to read as follows:

§ 488.61 Special procedures for approval and re-approval of organ transplant centers.

For the purposes of this subpart, the survey, certification, and enforcement procedures described at 42 CFR part 488, subpart A apply to transplant centers, including the periodic review of compliance and approval described at § 488.20.

(a) *Initial approval procedures for transplant centers that are not Medicare-approved as of June 28, 2007.* A transplant center, including a kidney transplant center, may submit a request to CMS for Medicare approval at any time.

(1) The request, signed by a person authorized to represent the center (for example, a chief executive officer), must include:

(i) The hospital's Medicare provider I.D. number;

(ii) Name(s) of the designated primary transplant surgeon and primary transplant physician; and,

(iii) A statement from the OPTN that the center has complied with all data submission requirements.

(2) To determine compliance with the clinical experience and outcome requirements at § 482.80(b) and § 482.80(c), CMS will review the data contained in the most recent OPTN Data Report and 1-year patient and graft survival data contained in the most recent Scientific Registry of Transplant Recipient (SRTR) center-specific report.

(3) If CMS determines that a transplant center has not met the data submission, clinical experience, or outcome requirements, CMS may deny the request for approval or may review the center's compliance with the conditions of participation at § 482.72 through § 482.76 and § 482.90 through § 482.104 of this chapter, using the procedures described at 42 CFR part 488, subpart A, to determine whether the center's request will be approved. CMS will notify the transplant center in writing whether it is approved and, if approved, of the effective date of its approval.

(4) CMS will consider mitigating factors, including (but not limited to) the following in considering initial approval of a transplant center that does not meet the data submission, clinical experience, outcome requirements and other conditions of participation:

(i) The extent to which outcome measures are met or exceeded;

(ii) Availability of Medicare-approved transplant centers in the area; and

(iii) Extenuating circumstances (e.g., natural disaster) that may have a temporary effect on meeting the conditions of participation.

(iv) CMS will not approve any program with a condition-level deficiency. However, CMS may approve a program with a standard-level deficiency upon receipt of an acceptable plan of correction.

(5) If CMS determines that a transplant center has met the data submission, clinical experience, and outcome requirements, CMS will review the center's compliance with the conditions of participation contained at § 482.72 through § 482.76 and § 482.90 through § 482.104 of this chapter using the procedures described at 42 CFR part 488, subpart A. If the transplant center is found to be in compliance with all the conditions of participation at § 482.72 through § 482.104, except for § 482.82 of this chapter (Re-approval Requirements), CMS will notify the transplant center in writing of the effective date of its Medicare-approval. CMS will notify the transplant center in writing if it is not Medicare-approved.

(6) A kidney transplant center may submit a request for initial approval after performing at least 3 transplants over a 12-month period.

(7) Transplant centers will be approved for 3 years.

(b) *Initial approval procedures for transplant centers, including kidney transplant centers, that are Medicare approved as of June 28, 2007.*

(1) A transplant center that wants to continue to be Medicare approved must be in compliance with the conditions of participation at §§ 482.72 through 482.104 as of June 28, 2007 and submit a request to CMS for Medicare approval under the conditions of participation no later than December 26, 2007, using the process described in paragraph (a)(1) of the section.

(2) CMS will determine whether to approve the transplant center, using the procedures described in paragraphs (a)(2) through (a)(5) of this section. Until CMS makes a determination whether to approve the transplant center under the conditions of participation at §§ 482.72 through 482.104, the transplant center will continue to be Medicare approved under the end stage renal disease (ESRD) conditions for coverage (CfCs) in part 405, subpart U of this chapter for kidney transplant centers or the pertinent national coverage decisions (NCDs) for extra-renal organ transplant centers, as applicable, and the transplant center will continue to be reimbursed for services provided to Medicare beneficiaries.

(3) Once CMS approves a kidney transplant center under the conditions of participation, the ESRD CfCs no longer apply to the center as of the date of its approval. Once CMS approves an extra-renal organ transplant center under the conditions of participation, the NCDs no longer apply to the center as of the date of its approval.

(4) If a transplant center that is Medicare approved as of June 28, 2007 submits a request for approval under the CoPs at §§ 482.72 through 482.104 of this chapter but CMS does not approve the transplant center, or if the transplant center does not submit its request to CMS for Medicare approval under the CoPs by December 26, 2007, CMS will revoke the transplant center's approval under the conditions for coverage for kidney transplant centers or the national coverage decisions for extra-renal transplant centers, as applicable, and the transplant center will no longer be reimbursed for services provided to Medicare beneficiaries. CMS will notify the transplant center in writing of the effective date of its loss of Medicare approval.

(c) *Re-approval procedures.* Once Medicare-approved, transplant centers, including kidney transplant centers, must be in compliance with all the conditions of participation for transplant centers at § 482.72 through § 482.104 of this chapter, except for § 482.80 (initial approval requirements) throughout the 3-year approval period.

(1) Prior to the end of the 3-year approval period, CMS will review the transplant center's data in making re-approval determinations.

(i) To determine compliance with the data submission requirements at § 482.82(a) of this chapter, CMS will request data submission data from the OPTN for the previous 3 calendar years.

(ii) To determine compliance with the clinical experience and outcome requirements at § 482.82(b) and § 482.82(c) of this chapter, CMS will review the data contained in the most recent OPTN Data Report and 1-year patient and graft survival data contained in the most recent SRTR center-specific reports.

(2) If CMS determines that a transplant center has not met the data submission, clinical experience, or outcome requirements at § 482.82, the transplant center will be reviewed for compliance with § 482.72 through § 482.76 and § 482.90 through § 482.104 of this chapter, using the procedures described at 42 CFR part 488, subpart A.

(3) If CMS determines that a transplant center has met the data submission, clinical experience, and outcome requirements at § 482.82, CMS may choose to review the transplant center for compliance with § 482.72 through § 482.76 and § 482.90 through § 482.104 of this chapter, using the procedures described at 42 CFR part 488, subpart A.

(4) CMS will consider mitigating factors, including (but not limited to) the following in considering re-approval of a transplant center that does not meet the data submission, clinical experience, outcome requirements and other conditions of participation:

(i) The extent to which outcome measures are met or exceeded;

(ii) Availability of Medicare-approved transplant centers in the area; and

(iii) Extenuating circumstances (*e.g.*, natural disaster) that may have a temporary effect on meeting the conditions of participation.

(iv) CMS will not approve any program with a condition-level deficiency. However, CMS may re-approve a program with a standard-level deficiency upon receipt of an acceptable plan of correction.

(5) CMS will notify the transplant center in writing if its approval is being revoked and of the effective date of the revocation.

(d) *Loss of Medicare Approval.* Centers that have lost their Medicare approval may seek re-entry into the Medicare program at any time. A center that has lost its Medicare approval must:

(1) Request initial approval using the procedures described in § 488.61(a);

(2) Be in compliance with §§ 482.72 through 482.104 of this chapter, except for § 482.82 (Re-approval Requirements), at the time of the request for Medicare approval; and

(3) Submit a report to CMS documenting any changes or corrective actions taken by the center as a result of the loss of its Medicare approval status.

(e) Transplant Center Inactivity. A transplant center may remain inactive and retain its Medicare approval for a period not to exceed 12 months during the 3-year approval cycle. A transplant center must notify CMS upon its voluntary inactivation as required by § 482.74(d) of this chapter.

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/MR AND CERTAIN NFs IN THE MEDICAID PROGRAM

■ 11. The authority citation for part 498 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions

§ 498.2 [Amended]

■ 12. In § 498.2, the definition of ''provider'' is amended by adding ''transplant center'' after ''hospital'' the first time it appears.

(Catalog of Federal Domestic Assistance Program No. 13.773 Medicare—Hospital Insurance Program; and No. 13.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 7, 2006.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: December 12, 2006.

Michael O. Leavitt

Secretary.

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Hydrocele Repair in Adults

Plain Language Summary:
Background: Consideration for coverage for adults for swelling or fluid collection in the scrotum. Left unrepaired, this can result in a hernia.

Should OHP cover this treatment? Staff recommends extending coverage for repair to adults because repair of hernias in any age is now covered.

Question: Should there continue to be limitations on hydrocele repair to children through age 18?

Question source: Ombuds office

Issue: A hydrocele is a type of swelling in the scrotum that occurs when fluid collects in the thin sheath surrounding a testicle. Hydrocele is common in newborns and usually disappears without treatment by age 1. Older boys and adult men can develop a hydrocele due to inflammation or injury within the scrotum. Hydroceles can be asymptomatic or cause pain. A symptomatic hydrocele can be surgically removed. Non-repaired communicating hydroceles can lead to inguinal hernia formation.

Recently, the Ombuds office had a case involving a recent immigrant who had a hydrocele causing pain that had not been repaired in childhood. The guideline note limiting hydrocele repair led to a denial of repair for him.

The current guideline was adopted in 2007, when hernias of any type were not repaired in persons over the age of 18.

HERC staff have done a data review, and found multiple claims for hydrocele repair in adults, all of which were paid. There were 111 paid claims for patients over age 18 between 1/2018 and 1/2022.

All private payers cover repair of hydroceles regardless of age.

Current Prioritized List status
Line 168 COMPLICATED HERNIAS; PERSISTENT HYDROCELE
Treatment: REPAIR
ICD-10-CM
- N43.0 Encysted hydrocele
- N43.2 Other hydrocele
- N43.3 Hydrocele, unspecified
- P83.5 Congenital hydrocele

Line 545 HYDROCELE
Treatment: MEDICAL THERAPY, EXCISION
ICD-10-CM
- N43.3 Hydrocele, unspecified
- N43.4 Spermatocele of epididymis
- N50.89 Other specified disorders of the male genital organs
- P83.5 Congenital hydrocele

GUIDELINE NOTE 63, HYDROCELE REPAIR

Line 168

Excision of hydrocele is only covered for children age 18 and younger with hydroceles which persist after 18 months of age.

HERC staff recommendations:

1) Change the name of line 545 to HYDROCELE IN INFANTS, SPERMATOCELE
2) Modify GN 63 as shown below

GUIDELINE NOTE 63, HYDROCELE REPAIR

Line 168,545

Excision of hydrocele is only included on this line ~~covered~~ for ~~children age 18 and younger with~~ hydroceles which persist after 18 months of age. For children under 18 months of age, it is included on line 545.

Below the Line Review Summary

Color Key	
	Topics under development
	Upcoming discussion topics
	Reviewed but no changes planned
	Already approved changes

Request source	Topic Description	Meeting Date	Planned Imp. Date	Summary of change (or recommended change, decision not to change)
Staff review	Deformities of upper body and all limbs	10/6/2022		Housekeeping changes recommended
Staff review	Congenital anomalies of knee (Knee problems since birth)	10/6/2022		No changes recommended
Staff review	Genitourinary with minimal or no treatment required (genital and urinary organs)	10/6/2022		Reviewed with urology, minor changes recommended
Dr. Hoffman	Congenital ear anomalies without hearing impairment	10/6/2022		Coverage of microtia with a new guideline is recommended after consultation with pediatric ENT
Staff review	Deformities of foot	10/6/2022		Housekeeping changes recommended
Staff review	Somatic symptoms line (Extreme feelings and anxiety about physical symptoms)	10/6/2022		Reviewed with BHAP, housekeeping changes recommended
BHAP request	Personality disorders	11/17/2022		Reviewed with BHAP, further claims review needed
Staff review	Broader Orthopedic review	11/17/2022		HERC staff will look through denied claims for candidates for review
Dr. Hoffman	Conduct disorder/impulse disorders (A type of behavior disorder)	8/11/2022	1/1/2022	BHAP recommended adding to funded region
Staff review	Behavioral health coding	8/11/2022	1/1/2022	Based on review of social emotional learning codes.
Staff review	Sleep disorders other than sleep apnea (including insomnia)	8/11/2022	1/1/2023	Consider adding insomnia above the funding line for cognitive behavioral therapy for insomnia (CBTi). Consider role of medication.

Request source	Topic Description	Meeting Date	Planned Imp. Date	Summary of change (or recommended change, decision not to change)
HSD nurse reviewer	Median and radial nerve lesions	8/11/2022	1/1/2022	Proposal to add to covered nerve lesion line with ulnar nerve lesions
Staff review	Benign neoplasm of the digestive system (Surgery for an abnormal growth found in the stomach or intestines)	5/19/2022		Added benign carcinoid tumors to funded region
HSD	Bilateral bone anchored hearing aids (BAHA) (A specific type of hearing aid for children)	5/19/2022	10/1/2022	Proposal to expand coverage from unilateral to bilateral
Staff review	Scrotal varices (An enlargement of the veins within the skin that holds the testicles (scrotum))	5/19/2022	10/1/2022	Already on line 327 as well as line 548 with no guideline. Propose to remove from line 548 and change name of line
Staff review	Other complications of a procedure	5/19/2022	10/1/2022	Propose to rename line "Minor" as diagnoses are minor
Staff review	Anemias due to kidney diseases (erythropoietin) (A drug to treat low blood count caused by kidney disease)	5/19/2022		Recommend clarifying coverage of erythropoietin for non-end stage kidney disease
Staff review	Esophageal ulcer	3/10/2022	10/1/2022	Added to funded region
Dr. Hoffman	Foreign body in digestive tract	3/10/2022	1/1/2022	Had already been addressed prior to the concern raised, but implementation was pending
Staff review	Generalized muscle weakness	3/10/2022	10/1/2022	Added to funded region
HSD Staff	Handicapping malocclusion	11/18/2021	1/1/2023	Working on implementation issues; addition to funded region planned for 1/1/2023
CCO	Dorsal rhizotomy	3/10/2022	10/1/2022	Added to funded region
Staff review	Corneal abcess	3/10/2022	10/1/2022	Added to funded region
Staff review	Lichen planus	3/12/2020	10/1/2022	Change name of line to reflect mild/moderate; severe forms on funded line as defined by Guideline Note 21
Staff review	Mastoiditis	3/12/2020	10/1/2022	Added to funded region
Dr. Hoffman	Nightmare disorder	11/18/2021	1/1/2022	Added to funded region

Request source	Topic Description	Meeting Date	Planned Imp. Date	Summary of change (or recommended change, decision not to change)
Dr. Hoffman	Oral candidiasis (thrush)	8/12/2021	10/1/2021	Added to funded region for feeding problems in newborns line
Dr. Hoffman	Phimosis (acquired penile complications, circumcision etc)	10/7/2021	1/1/2022	Clarified coverage criteria for acquired vs congenital anomalies of the penis. Added to funded region for acquired anomalies.
Staff review	Polydactyly	3/12/2020	10/1/2022	Clarified earlier decision to confirm in funded region
Public	Rhinoplasty/septoplasty/ deviated septum	8/12/2021	10/1/2022	Created new criteria for septoplasty, clarified conditions for coverage. Some new coverage and new limitations for services that would be cosmetic.
Advocates	Selective mutism	11/18/2021	1/1/2022	Moved to funded anxiety line
Staff review	Sjogren syndrome	3/10/2022	10/1/2022	Added to funded region
Staff review	Tendon and ligament injuries	3/10/2022	10/1/2022	Added to funded region for full tears
Staff review	Viral endocarditis, myocarditis, pericarditis, cardiomyopathy	3/10/2022	10/1/2022	Added to funded region
Staff review	Vitiligo	10/7/2021	1/1/2022	Added vitiligo as a funded condition. Affects children's social function
Staff review	Acquired torsion of penis	3/10/2022	10/1/2022	Added to funded region
Staff review	Agenesis of lung	3/10/2022	10/1/2022	Added to funded region for supportive care
EPSDT	Child growth and development	11/18/2021	1/1/2022	Added path to coverage for treatments supporting growth, development and participation in school for children
Staff review	Chronic pancreatitis		1/1/2022	Already merged for 2022 before this review
Staff review	Vitiligo of eyelid	3/10/2022	10/1/2022	Added to funded region
Staff (Val King)	Temporomandibular Joint Syndrome (TMJ) (Pain and dysfunction in the jaw joint and muscles controlling jaw movement)	8/11/2022		Review evidence; no change recommended at this time

Request source	Topic Description	Meeting Date	Planned Imp. Date	Summary of change (or recommended change, decision not to change)
Staff review	Physical therapy for minor musculoskeletal conditions (Injuries and disorders that affect the human body's movement or muscles, tendons, ligaments, nerves, discs, blood vessels, etc.)			Limited benefit; would be very difficult to implement
Dr. Hoffman	Allergic rhinitis (Nasal allergies/Hay fever)			No change; little impact on health except when comorbidity or growth/development/school exceptions apply
Dr. Hoffman	Angiodema (Swelling (edema) of the lower layer of skin and tissue just under the skin)	11/18/2021	1/1/2022	Removed unfunded duplicate line (no substantive change, was already covered)
Dr. Hoffman	Benign bone neoplasm			No change made; serious benign neoplasms are on line 401; Guideline 137 clarifies which are covered.
Dr. Hoffman	Congenital anomalies of female genital tract excluding vagina			No change: Diagnoses on this line have no treatment. Other anomalies that require repair are on funded line(s)
Dr. Hoffman	Dermatophytoses (ringworm, etc.)			No change; primary care and preferred medications should be sufficient for these conditions
Dr. Hoffman	Diaper rash			No change: Primary care and preferred medications (nystatin) should be sufficient
Dr. Hoffman	Dysmenorrhea			No change; primary care and preferred medications (NSAIDS, birth control) should be sufficient for these conditions
Dr. Hoffman	Hodeolum/chalazeon			No change; primary care and preferred meds should be sufficient for these conditions. Rare exceptions can be considered through existing processes
Dr. Hoffman	Mild eczema			No change; primary care and preferred medications should be sufficient for these conditions
Dr. Hoffman	Mild psoriasis			No change; primary care and preferred medications should be sufficient for these conditions

Request source	Topic Description	Meeting Date	Planned Imp. Date	Summary of change (or recommended change, decision not to change)
Dr. Hoffman	Minor burns			No change: Primary care and preferred medications should be sufficient
Advocates	Pica (Persistent eating of non-food items (for example clay, wool, lead, wood) at an age when it is considered to be developmentally inappropriate)	3/10/2022	10/1/2022	No change: Removed ambiguity of coverage for pica in children (should have already been in funded region), renamed line to clarify that the unfunded line is "Pica in adults"
Dr. Hoffman	Symptomatic urticaria			No change; primary care and preferred medications should be sufficient for these conditions
Staff review	Angiosarcoma of liver; intrahepatic bile duct carcinoma			Liver angiosarcoma has a very poor prognosis with any treatment (6 months even with surgery). Per NIH, the only treatment of bile duct carcinoma is palliative care
Staff review	Central retinal artery occlusion			Reviewed; no effective treatment is available
Dr. Hoffman	Conversion disorders F44.4-7, include non-epilectic seizures			Cognitive behavioral therapy would be available with another underlying disorder such as depression. No other treatment for actual disorder indicated
Staff review	Cysts of Bartholin's gland and vulva			N75.1 (Abscess of Bartholin's gland) is included on line 205. Cysts typically have no symptoms and do not need treatment
Staff review	Enophthalmos			Treatment is directed at underlying diseases, which appear in funded region
Dr. Hoffman	Infectious mononucleosis			Primary care should be sufficient; there is no treatment for this condition
Staff review	Miscellaneous rare congenital anomalies			Individual consideration will be required
Staff review	Nasal polyps			and saline. Surgery indicated if causing chronic sinusitis due to blockage of sinus ostia (would be covered on chronic sinusitis line)
Staff review	Personality disorders			No effective treatment

Request source	Topic Description	Meeting Date	Planned Imp. Date	Summary of change (or recommended change, decision not to change)
Staff review	Secondary and ill-defined neoplasms			Treatment should be targeted to primary cancer, which would be covered.
Staff review	Thrombosed and complicated hemorrhoids			Generally treated with fiber and observation. Could be addressed based on individual review
Staff review	Tension headaches			Primary care and NSAIDs are effective treatments.

2022 Below the Line Review
Deformities of Upper Body and All Limbs

Plain Language Summary:
Background: Review of select conditions currently below the funding level of the Oregon Health Plan. Line 528, Deformities of upper body and all limbs, has diagnosis (finding out the cause of an illness or condition) and treatment codes for certain conditions of upper body, arms, elbows, hands, fingers, hips, legs, feet, toes and joints.

Should OHP cover this treatment? Staff recommends removing the codes for many conditions from the uncovered lines because treatment for many of these conditions are already included on other covered lines. A diagnosis which is made using a general ("unspecified" or "other") code where a more specific code is available would continue to be not covered.

Issue: As part of the below the line review, advocates requested a review of diagnoses on line 528 DEFORMITIES OF UPPER BODY AND ALL LIMBS for possible re-prioritization.

Diagnoses on line 528

ICD-10-CM code	Code description	Comments
M20.00 family	Unspecified deformity of finger	
M20.01 family	Mallet finger	
M20.02 family	Boutonniere deformity of finger	Also on line 377 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
M20.03 family	Swan-neck deformity of finger	Also on line 377
M20.09 family	Other deformity of finger	Also on line 377
M21.0 family	Valgus deformity of elbow, hip, knee, ankle	Also on line 377
M21.1 family	Varus deformity of elbow, hip, knee	Also on line 377
M21.2 family	Flexion deformity, shoulder, elbow, wrist, fingers, hip, knees, toes	Also on line 377
M21.3 family	Foot drop	Also on line 377
M21.519	Acquired clawhand, unspecified hand	Specific hands are on line 377
M21.52 family	Acquired clubhand	Also on line 377
M21.7 family	Unequal limb length (acquired), arm and leg bones	Also on line 377
M21.8 family	Other specified acquired deformities of arm or leg	Also on line 377
M21.9 family	Unspecified acquired deformity of arm or leg	Also on line 377

2022 Below the Line Review
Deformities of Upper Body and All Limbs

M24.03-M24.05 families	Loose body in wrist, finger, hip	Also on line 359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
M24.12-M54.14 families	Other articular cartilage disorders in elbow, wrist, hand	
M24.15 family	Other articular cartilage disorders in hip	Also on line 356
M24.444-M24.446	Recurrent finger dislocation	
M24.6 family	Ankylosis of elbow, hand, hip	Abnormal stiffening of joint due to fusion of the bones
M24.7	Protrusio acetabuli	Rare condition in which the head of the femur protrudes into the pelvis
M24.8 family	Other specific joint derangements of elbow, wrist, hand, hip	Most also on line 359 (other than not specified codes)
M25.1 family	Fistula, shoulder, elbow, wrist, hand, hip, knee, ankle, foot	Very rare, generally a surgical complication. Hip fistulas are also on line 359
M25.2 family	Flail joint, elbow, wrist, hand, hip, knee	Excessive or abnormal degree of mobility in a joint
M25.3 family	Other instability, elbow, wrist, hand, hip, knee	More specific codes are on covered lines
M25.8 family	Other specified joint disorders, elbow, wrist, hand, hip, knee	More specific codes are on covered lines
M72.1	Knuckle pads	Benign fibrofatty subcutaneous pads over finger joints
M72.4	Pseudosarcomatous fibromatosis	Very rare disease
M85.9	Disorder of bone density and structure, unspecified	Specified codes are covered
M89.1 family	Complete or partial physeal arrest, humerus, radius, femur, tibia	Growth arrest generally caused by trauma. No treatments available
M89.2 family	Other disorders of bone development and growth, various arm and leg bones	
M89.7 family	Major osseous defect, shoulder, arm, pelvis, leg	Bone loss
M89.9	Disorder of bone, unspecified	
M92.0 and M92.1 family	Juvenile osteochondrosis of humerus, radius or ulna	“growing pains” in joint
M92 family	Juvenile osteochondrosis of hand	

2022 Below the Line Review
Deformities of Upper Body and All Limbs

M93.1	Kienbock's disease of adults	Interruption of blood supply to the lunate bone in the wrist. Surgery is available using other codes
M93.8 family	Other specified osteochondropathies of arm or leg	Specified codes are on covered lines
M93.9 family	Osteochondropathy, unspecified of arm or leg	
M94.9	Disorder of cartilage, unspecified	
M95.5	Acquired deformity of pelvis	
M95.8	Other specified acquired deformities of musculoskeletal system	
M99.8 family	Other biomechanical lesions of lower extremity	
Q65.9	Congenital deformity of hip, unspecified	
Q67.6	Pectus excavatum	Also on line 401 BENIGN CONDITIONS OF BONE AND JOINTS AT HIGH RISK FOR COMPLICATIONS
Q68 family	Congenital deformity of finger(s) and hand, knee, leg bones	Knee, finger and hand diagnoses also on covered lines. Other codes are for bowing of the leg bones
Q72.70	Split foot, unspecified lower limb	Also on line 359
Q74 family	Other congenital malformations of upper limb	Upper limb and shoulder codes on line 359
Q76.6-Q76.9	Congenital malformation of thorax	
Q79.6 family	Ehlers-Danlos syndrome	Congenital condition resulting in loose joints. No treatment available
Q79.8	Other congenital malformations of musculoskeletal system	

2022 Below the Line Review
Deformities of Upper Body and All Limbs

HERC staff summary

Treatment, including physical therapy, is available for many of the diagnoses on line 528 on other covered lines. Diagnoses solely on line 528 have no available treatments or are unspecified diagnoses where a more specific diagnosis (for example, a specific hand) is on a covered line. Note: "other specified" diagnosis codes should remain on a covered and uncovered line if they appear on both as some sub-diagnoses may require treatment and some may not. However, staff recommends removal of all diagnoses from line 528 that appear on covered lines as a housekeeping item to simplify claims processing.

HERC staff recommendations:

1) Remove the ICD-10-CM codes shown below from line 528 DEFORMITIES OF UPPER BODY AND ALL LIMBS and leave on other current lines

ICD-10-CM code	Code description	Comments
M20.02 family	Boutonniere deformity of finger	Also on line 377 Dysfunction line
M20.03 family	Swan-neck deformity of finger	Also on line 377
M20.09 family	Other deformity of finger	Also on line 377
M21.0 family	Valgus deformity of elbow, hip, knee, ankle	Also on line 377
M21.12-M21.16 families	Varus deformity of elbow, hip, knee	Also on line 377
M21.2 family	Flexion deformity, shoulder, elbow, wrist, fingers, hip, knees, toes	Also on line 377
M21.37 family	Foot drop	Also on line 377
M21.52 family	Acquired clubhand	Also on line 377
M21.7 family	Unequal limb length (acquired), arm and leg bones	Also on line 377
M21.8 family	Other specified acquired deformities of arm or leg	Also on line 377
M21.90-M21.05 families	Unspecified acquired deformity of arm or leg	Also on line 377
M24.03-M24.05 families	Loose body in wrist, finger, hip	Also on line 359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
M24.15 family	Other articular cartilage disorders in hip	Also on line 356
M25.15 family	Fistula, hip	Also on line 359
Q67.6	Pectus excavatum	Also on line 401 BENIGN CONDITIONS OF BONE AND JOINTS AT HIGH RISK FOR COMPLICATIONS
Q72.70	Split foot, unspecified lower limb	Also on line 359

2022 Below the Line Review
Congenital Anomalies of Knee

Plain Language Summary:
Background: This is a review of select conditions currently below the Oregon Health Plan's (OHP) funding level; conditions of the knee present since birth such as plica syndrome. A plica is a fold in the casing that protects knee joints; most people have four folds in each knee. Sometimes the plica located in the middle of your knee becomes irritated. This is called plica syndrome and it causes pain, swelling and instability. Treatment is usually rest, stretching, anti-inflammatory medication (such as Advil) and exercises.

Other considered conditions are deformity of the knee and malformation of the knee present since birth; there are no treatments for these conditions.

Should OHP cover this treatment? Staff recommends no change in prioritization on OHP because there is no treatment for the conditions or treatment is managed by a primary care visit.

Issue: As part of the below the line review, advocates requested a review of diagnoses on line 599 CONGENITAL DEFORMITIES OF KNEE for possible re-prioritization.

Diagnoses on line 599

ICD-10-CM code	Code description	Subdiagnoses
M67.5 family	Plica syndrome	
Q68.2	Congenital deformity of knee	Congenital knee dislocation, genu recurvatum (knee hyperextension)
Q74.1	Congenital malformation of knee	Congenital absence of patella, congenital genu valgum (knock knees), congenital genu varum (bow legs)

Similar codes:
S83.19 family (dislocation of knee) is on line 359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS

Information regarding diagnoses:

1) Plica syndrome: Plica is a fold in the membrane of the knee joint. Patients with plica syndrome will experience pain on the anterior aspect of the knee associated with clicking or popping. Treatment is generally conservative, involving rest, stretching, NSAIDs and exercises. Steroid injections may be used if conservative treatment is not effective. In rare cases, arthroscopic knee surgery is used to remove the plica. Surgery is generally considered only in refractory cases, as it can cause further irritation and scarring of the synovial plica.
    a. Evidence for effectiveness of surgery consists of case series of 100-300 patients
2) Genu valgum and genu varum are conditions that do not have any treatments. They resolve as a child grows. Genu varum may be caused by vitamin deficiencies, particularly vitamin D deficiency (rickets), and that deficiency would be covered for treatment.

2022 Below the Line Review
Congenital Anomalies of Knee

HERC staff recommendation:

1) Make no change in prioritization of diagnoses on line 599 CONGENITAL DEFORMITIES OF KNEE

2022 Below the Line Review
CONGENITAL ANOMALIES OF THE EAR WITHOUT IMPAIRMENT OF HEARING; UNILATERAL ANOMALIES OF THE EAR

Plain Language Summary:
Background: This is a review of select conditions currently below the Oregon Health Plan's (OHP) funding level; conditions of the ear present since birth that do not impact hearing are on line 602. Types 1-3 of *small ear (microtia)* are also on line 602. Type 4 *(anotia)* is the most severe (all of the ear is missing) and is covered on line 406.

Should OHP cover this treatment? Staff recommends coverage of these conditions under certain circumstances (for example: where hearing improvement is expected or surgery is needed to use hearing aids) because of expert recommendations.

Issue: As part of the below the line review, advocates requested a review of diagnoses on line 602 CONGENITAL ANOMALIES OF THE EAR WITHOUT IMPAIRMENT OF HEARING; UNILATERAL ANOMALIES OF THE EAR for possible re-prioritization.

Diagnoses on line 602

ICD-10-CM code	Code description	Subdiagnoses/comments
Q16.2	Absence of eustachian tube	
Q17.0	Accessory auricle	
Q17.1	Macrotia	Large ear
Q17.2	Microtia	
Q17.3	Other misshapen ear	
Q17.4	Misplaced ear	
Q17.5	Prominent ear	
Q17.8	Other specified congenital malformations of ear	Subdiagnoses include split ear lobe, cryptotia (malformation of the cartilage of the upper ear)
Q17.9	Congenital malformation of ear, unspecified	
Z01.12	Encounter for hearing conservation and treatment	On multiple covered lines

Additional information
Microtia: There are four types of microtia, ranging from Type 1 to Type 4. Type 1 is the mildest form, where the ear retains its normal shape, but is smaller than usual. Type 4 is the most severe type where all external ear structures are missing —anotia. This condition can affect one or both ears. Anotia (ICD-10-CM Q16.1) is on line 406 BILATERAL ANOMALIES OF EXTERNAL EAR WITH IMPAIRMENT OF HEARING. The main concern with microtia is hearing loss, which would be eligible for treatment on the funded hearing loss line (line 311). Surgery is used to reconstruct the external ear, and an ear prosthetic can be created to replace a missing ear.

2022 Below the Line Review
CONGENITAL ANOMALIES OF THE EAR WITHOUT IMPAIRMENT OF HEARING; UNILATERAL ANOMALIES OF THE EAR

Expert guidelines

AAO-HNS 2013

The American Academy of Otolaryngology—Head and Neck Surgery ("AAO-HNS") recognizes microtia and anotia as congential birth defects. These conditions are associated with appreciable psychological and functional ramifications if left untreated. Reconstructive surgery is appropriate as a primary treatment in both children and adults. Therefore, microtia and anotia shall be considered reconstructive surgery to restore a missing or significantly deformed body part visibly present under normal circumstances.

Expert input:

Dr. Peggy Kelley, pediatric otolaryngologist

1) Microtia/Atresia:
    a. Hearing loss can be improved with 1) BAHA, other bone attached aids like Bonebridge, Adhear and more technologies that are coming, or 2) surgery to open the ear canal -IF the patient has very favorable anatomy.
    b. Surgical opening of an ear canal needs some form of cover for the ear canal both for safety and appearance. Our ear canal is both curved and has an overhang (outer ear) to prevent ear drum and ear bone injury. A surgical canal is straight and is both not safe and really creepy to just look straight down to an ear canal. Therefore in order to have all hearing option available, it is necessary to be able to either have a prosthetic ear by an anaplastologist or a surgical ear of Medpore or autologous cartilage. All options are viable and the risk/benefit profiles that make one a better choice that another vary by patient and expertise of available specialists.
2) Ear Anomalies: Macrotia/microtia/prominotia, cryptotia, clefted ear lobes, etc.
    a. Ear anomalies may be part of the manifestation for a syndrome and should have a full medical/ENT evaluation.
    b. There is a standard typical or normal ear size and shape that has been determined. This fits our expectation of symmetry and what makes a face "human".
    c. The ability to wear "hearables" for communication such as hearing aids, AirPods and other earbuds are expected part of today's communication. An abnormally shaped ear can limit those options.
    d. Deviation from a standard is a congenital malformation and can be as devastating as a cleft lip psychologically to a patient. A cleft lip alone is not a life threatening malformation and yet it is covered. Speech, dental expectations and cosmesis are all covered.
    e. If an ear anomaly is > 2 standard deviations from normal in projection or the ear is asymmetric or the expected anatomic parts are not present or visible, it would be appropriate to consider coverage.

Other payer policies:

1) **Aetna 2022:** covers Q16.x (congenital ear anomalies with hearing loss) but not Q17.x
    a. Otoplasty/Pinnaplasty: Considered medically necessary when performed to improve hearing by directing sound in the ear canal, whether the ears are absent or deformed

from trauma, surgery, disease, or congenital defect. Otoplasty to correct large or protruding ears is considered cosmetic when the surgery will not improve hearing;

2) Cigna 2022

a. External ear reconstruction for the treatment of an external ear deformity or the absence of an external ear is considered medically necessary when ANY of the following criteria is met:
    i. hearing is expected to improve
    ii. reconstruction is necessary to allow the use of a conventional air conduction hearing aid
    iii. photographs demonstrate that the external ear deformity is preventing the functional ability to use eyewear for the correction of visual loss
b. Non-surgical external ear molding is considered medically necessary for a congenital external ear malformation with a functional impairment of hearing.
c. Each of the following are considered cosmetic in nature and not medically necessary when performed solely to improve physical appearance:
    i. external ear reconstruction
    ii. ear molding Otoplasty (CPT® code 69300) is considered cosmetic in nature and not medically necessary for ANY indication, including ALL of the following:
        1. prominent/protruding ears
        2. lop ears
        3. cupped ears
        4. constricted ears

2022 Below the Line Review
CONGENITAL ANOMALIES OF THE EAR WITHOUT IMPAIRMENT OF HEARING; UNILATERAL ANOMALIES OF THE EAR

HERC staff summary

Current coverage of congenital ear anomalies allows reconstruction when there is hearing loss for anotia. There are cases of microtia which are less severe than anotia but which still could result in hearing impairment or other functional loss. Other diagnoses on line 602 could be treated if on individual review the treatment is found to be medically necessary.

HERC staff recommendation:

1) Add ICD-10-CM Q17.2 (Microtia) to line 406 BILATERAL ANOMALIES OF EXTERNAL EAR WITH IMPAIRMENT OF HEARING
2) Rename line 406 ~~BILATERAL~~ ANOMALIES OF EXTERNAL EAR WITH IMPAIRMENT OF HEARING
3) Add CPT 21086 (Impression and custom preparation; auricular prosthesis) to line 406
4) Adopt a new guideline for line 406 as shown below

GUIDELINE NOTE XXX MICROTIA

Line 406, 602

ICD-10-CM Q17.2 (microtia) is included on line 406 for external ear reconstruction when ANY of the following criteria are met:

1) Hearing is expected to improve; OR
2) Reconstruction is necessary to allow for use of a conventional air conduction hearing aid; OR
3) The external ear deformity is preventing the functional ability to use eyewear for the correction of visual loss; OR
4) The patient is under 21 years of age and reconstruction is determined to be medically appropriate and necessary after individual case review.

Otherwise this diagnosis is included on line 602.

2022 Below the Line Review
GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

Plain Language Summary:
Background: Review of select conditions currently below the funding line of the Oregon Health Plan, for urinary and genital organs on line 658 (Genitourinary conditions with no or minimally effective treatments or no treatment necessary).

Should OHP cover this treatment? Staff recommends no change to most of these condition placements because most of these conditions do not require medical treatment. However, staff recommends moving certain codes to a Health Services Division workup file and adding a code for bleeding from the uterus that is longer than usual or that occurs at an irregular time to a covered line, 423 (Menstrual bleeding disorders)

Issue: As part of the below the line review, advocates requested a review of diagnoses on line 658 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY for possible re-prioritization.

Diagnoses on line 658

Line 658 Diagnoses		
ICD-10 Code	**Description**	**Other lines where this code appears/comments**
D30.8	Benign neoplasm of other specified urinary organs	214 CANCER OF KIDNEY AND OTHER URINARY ORGANS 511 BENIGN NEOPLASM OF KIDNEY AND OTHER URINARY ORGANS
D30.9	Benign neoplasm of urinary organ, unspecified	99 END STAGE RENAL DISEASE 214,511
E28.0	Estrogen excess	
K64.4	Residual hemorrhoidal skin tags	
N28.81	Hypertrophy of kidney	
N28.83	Nephroptosis	Condition in which kidney is lower than normal
N28.89	Other specified disorders of kidney and ureter	includes renal mass, renal scarring, ureteral fistula, and ureterocele. All of these diagnoses have more specific ICD-10 codes on covered lines other than renal mass. Work up of renal mass (imaging, biopsy) would be covered as diagnosotic
N32.89	Other specified disorders of bladder	multiple subdiagnoses, all of which do not require treatment
N32.9	Bladder disorder, unspecified	Subdiagnoses include bladder disorder, mass of bladder and lesion of bladder
N33	Bladder disorders in diseases classified elsewhere	

2022 Below the Line Review
GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

Line 658 Diagnoses		
ICD-10 Code	**Description**	**Other lines where this code appears/comments**
N37	Urethral disorders in diseases classified elsewhere	
N39.8	Other specified disorders of urinary system	No subdiagnoses
N42.30	Unspecified dysplasia of prostate	515 CHRONIC PROSTATITIS, OTHER DISORDERS OF PROSTATE Dysplasia of the prostate does not require treatment
N42.31	Prostatic intraepithelial neoplasia	515
N42.32	Atypical small acinar proliferation of prostate	515
N42.39	Other dysplasia of prostate	515
N44.1	Cyst of tunica albuginea testis	Benign mass external to the testicle
N44.2	Benign cyst of testis	
N44.8	Other noninflammatory disorders of the testis	
N48.6	Induration penis plastica	Also known as Peyronie's disease. GN73 PENILE ANOMALIES requires a condition to be caused by surgery to be eligible for treatment in adults. Peyronie's disease is ideopathic
N48.82	Acquired torsion of penis	424 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT with a guideline
N48.83	Acquired buried penis	424 with a guideline
N48.89	Other specified disorders of penis	424 with a guideline
N48.9	Disorder of penis, unspecified	
N50.89	Other specified disorders of the male genital organs	545 HYDROCELE
N50.9	Disorder of male genital organs, unspecified	
N51	Disorders of male genital organs in diseases classified elsewhere	
N83.321	Acquired atrophy of right fallopian tube	
N83.322	Acquired atrophy of left fallopian tube	
N83.329	Acquired atrophy of fallopian tube, unspecified side	

2022 Below the Line Review
GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

Line 658 Diagnoses		
ICD-10 Code	**Description**	**Other lines where this code appears/comments**
N83.6	Hematosalpinx	Blood in the fallopian tube. Normally caused by endometriosis or ectopic pregnancy, both of which are covered conditions
N83.9	Noninflammatory disorder of ovary, fallopian tube and broad ligament, unspecified	
N85.4	Malposition of uterus	
N85.6	Intrauterine synechiae	Only need treatment when causes fertility issues
N85.8	Other specified noninflammatory disorders of uterus	Subdiagnoses include calcification of uterus, cyst of urerus, atrophy of endometrium
N85.9	Noninflammatory disorder of uterus, unspecified	
N90.60	Unspecified hypertrophy of vulva	
N90.61	Childhood asymmetric labium majus enlargement	
N90.69	Other specified hypertrophy of vulva	No subdiagnoses found
N91.4	Secondary oligomenorrhea	Irregular periods. Primary oligomenorrhea (N91.3) is on DWF
N91.5	Oligomenorrhea, unspecified	Irregular periods. Primary oligomenorrhea (N91.3) is on DWF
N93.9	Abnormal uterine and vaginal bleeding, unspecified	
N94.9	Unspecified condition associated with female genital organs and menstrual cycle	
N96	Recurrent pregnancy loss	DIAGNOSTIC WORKUP FILE (DWF)
N99.83	Residual ovary syndrome	
Q52.120	Longitudinal vaginal septum, nonobstructing	
Q54.0	Hypospadias, balanic	434 HYPOSPADIAS AND EPISPADIAS with a guideline
Q54.4	Congenital chordee	434 with a guideline
Q54.9	Hypospadias, unspecified	
Q55.0	Absence and aplasia of testis	
Q55.1	Hypoplasia of testis and scrotum	

2022 Below the Line Review
GENITOURINARY CONDITIONS WITH NO OR MINIMALLY
EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

Line 658 Diagnoses		
ICD-10 Code	**Description**	**Other lines where this code appears/comments**
Q55.20	Unspecified congenital malformations of testis and scrotum	
Q55.21	Polyorchism	
Q55.22	Retractile testis	93 UNDESCENDED TESTICLE with a guideline
Q55.29	Other congenital malformations of testis and scrotum	
Q55.61	Curvature of penis (lateral)	434 with a guideline
Q55.62	Hypoplasia of penis	434 with a guideline
Q55.63	Congenital torsion of penis	434 with a guideline
Q55.64	Hidden penis	434 with a guideline
Q55.69	Other congenital malformation of penis	434 with a guideline
Q55.7	Congenital vasocutaneous fistula	
Q55.8	Other specified congenital malformations of male genital organs	
Q55.9	Congenital malformation of male genital organ, unspecified	
Q60.3	Renal hypoplasia, unilateral	86 CONGENITAL ANOMALIES OF GENITOURINARY SYSTEM with a guideline
Q62.4	Agenesis of ureter	86 with a guideline
Q62.5	Duplication of ureter	86 with a guideline
Q62.60	Malposition of ureter, unspecified	86 with a guideline
Q62.61	Deviation of ureter	86 with a guideline
Q62.62	Displacement of ureter	86 with a guideline
Q63.0	Accessory kidney	86 with a guideline
Q63.1	Lobulated, fused and horseshoe kidney	86 with a guideline
Q63.2	Ectopic kidney	86 with a guideline
Q63.3	Hyperplastic and giant kidney	86 with a guideline
Q63.8	Other specified congenital malformations of kidney	86 with a guideline

2022 Below the Line Review
GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

Line 658 Diagnoses		
ICD-10 Code	**Description**	**Other lines where this code appears/comments**
Q63.9	Congenital malformation of kidney, unspecified	86 with a guideline
Q64.11	Supravesical fissure of urinary bladder	
Q64.70	Unspecified congenital malformation of bladder and urethra	
Q64.72	Congenital prolapse of urinary meatus	
Q64.75	Double urinary meatus	
Q64.8	Other specified congenital malformations of urinary system	
Q64.9	Congenital malformation of urinary system, unspecified	
R39.81	Functional urinary incontinence	457 URINARY INCONTINENCE with a guideline
R80.2	Orthostatic proteinuria, unspecified	

Expert input:
Brian Duty, MD, urologist at OHSU, concurs that the urology diagnoses on this line do not require treatment other than ones that are also on covered lines with guidelines.

2022 Below the Line Review
GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

HERC staff summary

The majority of conditions on this line have no treatment, do not require treatment, are on another line that is covered when guideline criteria are met, or need diagnostic testing which is covered. This line was extensively reviewed by urologists in 2012 during the ICD-10 review and many of these diagnoses were moved to this line at that time as not needing treatment. A couple of diagnoses should be moved to be consistent with similar diagnoses on covered lines or lists.

HERC staff recommendations:

1) Remove ICD-10-CM N91.4 (Secondary oligomenorrhea) and N91.5 (Oligomenorrhea, unspecified) from line 658 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
    a. Advise HSD to add to the DIAGNOSTIC WORKUP FILE (DWF)
    b. Will match ICD-10-CM N91.3 (Primary oligomenorrhea)
    c. Allows diagnostic testing and treatment with birth control pills or other options
2) Add ICD-10-CM N93.9 (Abnormal uterine and vaginal bleeding, unspecified) to line 423 MENSTRUAL BLEEDING DISORDERS and remove from line 658 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
    a. Will match other abnormal uterine bleeding codes

CPAP Titration

Plain Language Summary:
Background: An overnight sleep test used to correctly set the pressure (continuous positive airway pressure (CPAP)) on an in-home machine used to treat people with sleep apnea. The first test is covered on OHP. Should OHP cover repeat tests to adjust the CPAP device?

Should OHP cover this treatment? Staff recommends covering up to two repeat sleep tests per year when certain factors occur (for example: weight change, worsening health conditions related to sleep apnea) because while there is limited evidence most private insurance companies allow two tests per year.

Question: Should the obstructive sleep apnea diagnostic guideline be modified to specify when and how often repeat sleep studies for Continuous Positive Airway (CPAP) titration are covered?

Question source: Providence CCO

Issue: The current guideline for diagnosis of obstructive sleep apnea (OSA) lists criteria for when initial sleep studies are covered. Providence CCO reviewers are seeing multiple requests for CPAP titrations (CPT 95811) after a diagnostic sleep study. The CCO is requesting clarification of coverage for repeat sleep studies/CPAP titration studies.

Current Prioritized List status
Both of the following are on the DIAGNOSTIC PROCEDURES file:

CPT **95810** Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist

CPT **95811** Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bilevel ventilation, attended by a technologist

DIAGNOSTIC GUIDELINE D8, DIAGNOSTIC TESTING FOR OBSTRUCTIVE SLEEP APNEA (OSA)
For adults over the age of 18 years:

A) For patients with clinical signs and symptoms consistent with obstructive sleep apnea (OSA), a home sleep study is the first-line diagnostic test for most patients, when available.
    1) For portable devices, Type II-III are included on this line. Type IV sleep testing devices must measure three or more channels, one of which is airflow, to be included on this line. Sleep testing devices that are not Type I-IV and measure three or more channels that include actigraphy, oximetry, and peripheral arterial tone, are included on this line.

B) Polysomnography in a sleep lab is indicated as a first-line test for patients with significant cardiorespiratory disease, potential respiratory muscle weakness due to a neuromuscular condition, awake hypoventilation or suspicion of sleep related hypoventilation, chronic opioid medication use, history of stroke or severe insomnia.

C) If a patient has had an inconclusive (or negative) home sleep apnea test and a clinical suspicion for OSA remains, then attended polysomnography is included on this line. Split night diagnostic protocols are required when a diagnosis of OSA is confirmed in the first portion of the night.

For children age of 18 or younger:

A) Obstructive sleep apnea (OSA) must be diagnosed by

1) nocturnal polysomnography with an AHI >5 episodes/h or AHI >1 episodes/h with history and exam consistent with OSA, OR
2) nocturnal pulse oximetry with 3 or more SpO2 drops <90% and 3 or more clusters of desaturation events, or alternatives desaturation (>3%) index >3.5 episodes/h,OR
3) use of a validated questionnaire (such as the Pediatric Sleep Questionnaire or OSA 18), OR
4) consultation with a sleep medicine specialist.

B) Polysomnography and/or consultation with a sleep medicine specialist to support the diagnosis of OSA and/or to identify perioperative risk is recommended for
1) high-risk children (i.e. children with cranio-facial abnormalities, neuromuscular disorders, Down syndrome, etc.)
2) children with equivocal indications for adenotonsillectomy (such as discordance between tonsillar size on physical examination and the reported severity of sleep-disordered breathing), children younger than three years of age

The development of this guideline note was informed by a HERC coverage guidance. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx

GUIDELINE NOTE 27, TREATMENT OF SLEEP APNEA

Line 202

For adults over the age of 18 years:

A) CPAP is covered initially when all of the following conditions are met:
1) 12 week 'trial' period to determine benefit. This period is covered if apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) is greater than or equal to 15 events per hour; or if between 5 and 14 events with additional symptoms including one or more of the following:
2) excessive daytime sleepiness defined as either an Epworth Sleepiness Scale score>10 or daytime sleepiness interfering with ADLs that is not attributable to another modifiable sedating condition (e.g. narcotic dependence), or
3) documented hypertension, or
4) ischemic heart disease, or
5) history of stroke
6) Additionally:
a) Providers must provide education to patients and caregivers prior to use of CPAP machine to ensure proper use; and
b) Positive diagnosis through polysomnogram (PSG) or Home Sleep Test (HST).

B) CPAP coverage subsequent to the initial 12 weeks is based on documented patient tolerance, compliance, and clinical benefit. Compliance (adherence to therapy) is defined as use of CPAP for at least four hours per night on 70% of the nights during a consecutive 30-day period.

C) Mandibular advancement devices (oral appliances) are covered for those for whom CPAP fails or is contraindicated.

D) Surgery for sleep apnea in adults is not included on this line (due to lack of evidence of efficacy). Surgical codes are included on this line only for children who meet criteria below

E) Hypoglossal nerve stimulation for treatment of obstructive sleep apnea is not included on this line due to insufficient evidence of effectiveness and evidence of harm.

For children age of 18 years or younger:

A) Adenotonsillectomy is an appropriate first line treatment for children with OSA. Adenoidectomy without tonsillectomy is only covered when a child with OSA has previously had a tonsillectomy,

when tonsillectomy is contraindicated, or when tonsillar hypertrophy is not present. More complex surgical treatments are only included on this line for children with craniofacial anomalies.

B) Intranasal corticosteroids are an option for children with mild OSA in whom adenotonsillectomy is contraindicated or for mild postoperative OSA.

C) CPAP is covered for a 3 month trial for children through age 18 who have
   1) undergone surgery or are not candidates for surgery, AND
   2) have documented residual sleep apnea symptoms (sleep disruption and/or significant desaturations) with residual
      daytime symptoms (daytime sleepiness or behavior problems)

D) CPAP will be covered for children through age 18 on an ongoing basis if:
   1) There is documentation of improvement in sleep disruption and daytime sleepiness and behavior problems with CPAP use, AND
   2) Annual re-evaluation for CPAP demonstrates ongoing clinical benefit and compliance with use, defined as use of CPAP for at least four hours per night on 70% of the nights in a consecutive 30 day period

The development of this guideline note was informed by a HERC coverage guidance. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx

Evidence

No reviews or expert guidelines were found regarding the frequency of repeat sleep studies. Sleep medicine specialists were consulted and recommended review of the American Academy of Sleep Medicine guidelines; however, no guidelines were found addressing repeat sleep studies.

Expert guidelines

1) **Choosing Wisely 2014**
   a. Don't perform positive airway pressure re-titration studies in asymptomatic, adherent sleep apnea patients with stable weight.
      i. Re-titration of positive airway pressure (PAP) is not indicated for adult obstructive sleep apnea patients with stable weight whose symptoms are well controlled by their current PAP treatment. Follow-up PSG or re-titration is indicated for adult patients who are again symptomatic despite the continued, proper use of PAP, especially if they have gained substantial weight (e.g. 10% of original weight) since the last titration study. A new diagnostic PSG or re-titration may be indicated for patients who have lost substantial weight, to determine whether PAP treatment is still necessary

Other payer policies

1) **Aetna 2022**
   a. It may be necessary to perform repeat sleep studies up to twice a year for *any* of the following indications. (Note: where repeat testing is indicated, attended full-channel nocturnal polysomnography (NPSG) (Type I device) performed in a healthcare facility is considered medically necessary for persons who meet criteria for attended NPSG in

section I above; in all other cases, unattended (home) sleep studies are considered medically necessary):

i. To determine whether positive airway pressure treatment (i.e., CPAP, bilevel positive airway pressure (BiPAP), demand positive airway pressure (DPAP), variable positive airway pressure (VPAP), or auto-titrating positive airway pressure (AutoPAP)) continues to be effective in persons with new or persistent symptoms, after interrogation of current positive airway pressure device; *or*

ii. To determine whether positive airway pressure treatment settings need to be changed in persons with new or persistent symptoms, after interrogation of current positive airway pressure device. (**Note**: This criterion does not apply to AutoPAP devices, as these devices are automatically titrated and do not require manual adjustment of treatment settings.); *or*

iii. For persons with substantial weight loss (loss of 10 percent or more body weight) or some other change in their medical condition that would affect the need for continued positive airway pressure treatment (e.g., heart attack, stroke, heart failure), to determine whether continued treatment with positive airway pressure treatment is necessary; *or*

iv. To assess treatment response after upper airway surgical procedures and after initial treatment with oral appliances.

2) Cigna 2021

a. Repeat Titration study can be performed if any of the following criteria is met:
   i. OSA currently on CPAP
      1. Re-assessment of treatment results for an individual with known OSA currently on CPAP therapy can be performed when any of the following has occurred:
         a. Substantial weight gain (10% of body weight) with return of symptoms.
         b. BMI decreases by 10% and there is intolerance of PAP pressure
         c. Clinical response is insufficient despite treatment
         d. Symptoms return despite a good initial response to CPAP
         e. Development of hypertension or worsening of hypertension despite a minimum of three months of adherent PAP usage.
         f. New onset decompensated heart failure or new stroke or TIA in a patient adherent to PAP therapy
         g. PAP machine download with AHI ≥5/hr with return of symptoms
         h. Must demonstrate that recurrent or continued symptoms are not due to insufficient compliance (must be using PAP >70% of nights, 4+hrs/night with continued symptoms).
         i. Results of previous medically necessary sleep test were inadequate and not diagnostic due to limited sleep time or other specified variables.
         j. NOT to assess for the efficacy of PAP therapy in the absence of recurrent or changed symptoms
         k. NOT to supply new PAP equipment.

b. OSA currently treated with bi-level PAP, APAP, ASV Re-assessment of treatment results (with CPT® 95811) for a patient with known OSA currently treated with bilevel PAP, APAP, ASV can be performed when any of the following has occurred:
   i. Substantial weight gain (10% of body weight) with return of symptoms.

ii. BMI decreases by 10% and there is intolerance of PAP pressure o Clinical response is insufficient despite treatment
iii. Symptoms return despite a good initial response to CPAP. o PAP machine download with AHI ≥5/hr with return of symptoms or ≥15/hr with or without return of symptoms.
iv. Must demonstrate that recurrent or continued symptoms are not due to insufficient compliance (must be using PAP ≥70% of nights, 4+hrs/night with continued symptoms).
v. Results of previous medically necessary sleep test were inadequate and not diagnostic due to limited sleep time or other specified variables.
vi. NOT to assess for the efficacy of PAP therapy in the absence of recurrent or changed symptoms
vii. NOT to supply new PAP equipment.

3. Carecentrix 2021

a. A repeat PSG, HSAT, or Split Night Study to confirm the diagnosis of sleep disorders meets the definition of medical necessity when the member meets previously stated criteria for a PSG, HSAT, or Split Night as outlined above and at least ONE of the following conditions is met:
    i. Recent HSAT (less than 1 year old) confirmed to be non-diagnostic:
        1. A previous home sleep study was technically inadequate and there was a valid attempt to retest the member via HSAT OR
        2. A previous home sleep study failed to establish the diagnosis of OSA in a member with a high pretest probability of OSA.
    ii. Member has had a significant change in weight that has impacted signs/symptoms of obstructive sleep apnea, specifically weight gain or weight loss of greater than or equal to 10% of total body weight, when re-evaluation is warranted to modify therapy.
    iii. Reassessment of clinical indicators of obstructive sleep apnea to determine the effectiveness of treatment after surgical intervention:
        1. Tonsillectomy,
        2. Adenoidectomy,
        3. Uvulopalatoplasty (UPPP),
        4. MaxillomandibularAdvancement Surgery (MMA)
        5. Other upper airway surgery/implantation for treatment of obstructive sleep apnea
    iv. Implementation and evaluation of a fabricated oral mandibular advancement appliance (OAT) by a qualified healthcare professional:
        1. Treatment efficacy of an oral mandibular appliance may be assessed using HSAT, OR
        2. An oral mandibular appliance may be adjusted manually during polysomnography to eliminate sleep disordered breathing in the sleep laboratory by a sleep technologist, and as prescribed by the qualified healthcare professional.
b. A repeat in-lab PAP titration (95811) meets the definition of medical necessity for a member who is known to have OSA when (1&2):
    i. A diagnostic sleep test has been submitted to confirm the diagnosis of OSA AND, any of the following:

1. The member is documented to have a recurrence of OSA related symptoms, such as snoring, excessive daytime somnolence, fatigue, disrupted sleep, etc. or persistent elevation in AHI documented from PAP device download while adherent to PAP therapy (use ≥4 hours per night on 70% of nights during a consecutive thirty (30) day period),
2. The member has a 10% change in body weight which has resulted in a recurrence of OSA-related symptoms,
3. The member has upper airway surgery, which has resulted in a recurrence of OSA-related symptoms,
4. Significant oxygen desaturation found during diagnostic testing:
    a. O2 saturation <90% for greater than 15 % of recording time during a diagnostic home sleep apnea test or diagnostic facility based PSG, OR
    b. O2 saturation < 80% for greater than 1% of recording time during a diagnostic home sleep apnea test or diagnostic facility based PSG

ii. The member is not a candidate for APAP based on the presence of co-morbid medical conditions or concomitant sleep disorders

Expert input:

Dr. Derek Lam, OHSU sleep medicine

Dr. Lam agreed with the HERC staff recommended wording regarding repeat studies. He had some concerns about applying these criteria to children, but the section with the added wording only applies to adults aged 18 and over.

CPAP Titration

HERC staff summary

There is a dearth of data on how often sleep studies need to be performed for patients on CPAP. The American Academy of Sleep Medicine does not have a specific guideline regarding repeat sleep studies other than a statement that re-titration is not needed in asymptomatic, adherent patients with stable weight. Major insurers have similar criteria for repeat sleep studies: recurrence of OSA symptoms, weight change of 10% of body weight, new or worsening health conditions related to OSA, and to assess treatment response after upper airway surgical procedures and after initial treatment with oral appliances. Some major insurers limit repeat sleep studies to twice per year.

HERC staff recommendation:

1) Modify Diagnostic Guideline D8 as shown below

DIAGNOSTIC GUIDELINE D8, DIAGNOSTIC TESTING FOR OBSTRUCTIVE SLEEP APNEA (OSA)

For adults over the age of 18 years:

A) For patients with clinical signs and symptoms consistent with obstructive sleep apnea (OSA), a home sleep study is the first-line diagnostic test for most patients, when available.
   1) For portable devices, Type II-III are included on this line. Type IV sleep testing devices must measure three or more channels, one of which is airflow, to be included on this line. Sleep testing devices that are not Type I-IV and measure three or more channels that include actigraphy, oximetry, and peripheral arterial tone, are included on this line.

B) Polysomnography in a sleep lab is indicated as a first-line test for patients with significant cardiorespiratory disease, potential respiratory muscle weakness due to a neuromuscular condition, awake hypoventilation or suspicion of sleep related hypoventilation, chronic opioid medication use, history of stroke or severe insomnia.

C) If a patient has had an inconclusive (or negative) home sleep apnea test and a clinical suspicion for OSA remains, then attended polysomnography is included on this line. Split night diagnostic protocols are required when a diagnosis of OSA is confirmed in the first portion of the night.

D) Repeat sleep studies are covered up to twice a year when one of the following has occurred:
   1) recurrence of OSA symptoms
   2) weight change of more than 10% of body weight
   3) new or worsening health conditions related to OSA
   4) upper airway surgical procedures or initial treatment with oral appliances

For children age of 18 or younger:

A) Obstructive sleep apnea (OSA) must be diagnosed by
   1) nocturnal polysomnography with an AHI >5 episodes/h or AHI >1 episodes/h with history and exam consistent with OSA, OR
   2) nocturnal pulse oximetry with 3 or more SpO2 drops <90% and 3 or more clusters of desaturation events, or alternatives desaturation (>3%) index >3.5 episodes/h,OR
   3) use of a validated questionnaire (such as the Pediatric Sleep Questionnaire or OSA 18), OR
   4) consultation with a sleep medicine specialist.

B) Polysomnography and/or consultation with a sleep medicine specialist to support the diagnosis of OSA and/or to identify perioperative risk is recommended for
   1) high-risk children (i.e. children with cranio-facial abnormalities, neuromuscular disorders, Down syndrome, etc.)

2) children with equivocal indications for adenotonsillectomy (such as discordance between tonsillar size on physical examination and the reported severity of sleep-disordered breathing), children younger than three years of age

The development of this guideline note was informed by a HERC coverage guidance. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx

Congenital Foot Deformity Code Review

Plain Language Summary:
Background: Foot and toe conditions present since birth (for example: "club foot," flat feet, very high arch).

Should OHP cover this treatment? Staff recommends only housekeeping changes.

Question: Where should various diagnoses in the Q66 (congenital foot deformities) code family be prioritized?

Question source: Bhavesh Rajani, MD, CCO medical director

Issue: There are multiple subdiagnoses in the Q66 family. Most were placed on the same line as the "parent code" as "child codes" when they were released as new ICD-10 codes without specific in-depth review. Dr. Rajani requested a review of this code family, as some of these codes are on funded lines and code for conditions such as flat feet which are not intended for coverage.

On review, several of the codes in this family should be moved to other lines.

Current Prioritized List status:

ICD-10-CM Code	Code description	Current code placement	Condition description
Q66.0	Congenital talipes equinovarus	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	"club foot"
Q66.1	Congenital talipes calcaneovarus	359	A form of club foot
Q66.21	Congenital metatarsus primus varus	543 DEFORMITIES OF FOOT	Related to bunions
Q66.22	Congenital metatarsus adductus	359	Causes "pigeon toe"
Q66.3	Other congenital varus deformities of feet	359	Subdiagnoses: Congenital hallux varus Talipes varus
Q66.4	Congenital talipes calcaneovalgus	359	"rocker bottom foot"
Q66.5	Congenital pes planus	579 CAVUS DEFORMITY OF FOOT; FLAT FOOT; POLYDACTYLY AND SYNDACTYLY OF TOES	Flat feet
Q66.6	Other congenital valgus deformities of feet	359	Subdiagnoses: Congenital hallux valgus, pes planus, talipes vulgus
Q66.7	Congenital pes cavus	359	Extremely high arch

			Dr. Seuferling input: need this code for orthotics particularly for diabetic patients
Q66.80-Q66.82	Congenital vertical talus deformity	543	"rocker bottom foot"
Q66.89	Other specified congenital deformities of feet	543	Subdiagnoses: Hammer toes, claw toes, contracture of toes
Q66.9	Congenital deformity of feet, unspecified	359	Subdiagnoses: Congenital toe deformities

Q66.6 (Other congenital valgus deformities of feet) is mainly used for pes planus (flat foot). The other subdiagnoses on this line include congenital hallux valgus which is a bunion like condition, as well as congenital talipes vulgus which is a rare and debilitating condition.

Q66.9 codes mainly for congenital toe anomalies, most of which are found on line 543 DEFORMITIES OF FOOT.

HERC staff recommendations:

1) Add ICD-10-CM Q66.9x (Congenital deformity of feet, unspecified) to line 543 DEFORMITIES OF FOOT and remove from line 359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS

Plain Language Summary:
Background: Human growth hormone (HGH) fuels childhood growth and helps maintain tissues and organs throughout life. It's produced by the gland located at the brain's base (pituitary). Currently, OHP limits use of HGH to children who are not yet done growing. There are other important uses which should be considered for other conditions.

Should OHP cover this treatment? Staff recommends extensive changes to the current guideline to allow limited coverage of HGH for adults and allow individualized review for HGH needs for children.

Question: Should the growth hormone guideline be deleted or extensively modified?

Question source: advocates, OHA leadership, HERC staff, P&T staff

Issue: Over the past year, several concerns have arisen regarding Guideline Note 74 GROWTH HORMONE TREATMENT.

This medication has several different formulations which have indications applying to different pediatric populations, including endocrine disorders, developmental disorders and short stature. For adults they are indicated only for growth hormone deficiency, HIV wasting or cachexia and short bowel syndrome. The medication is sometimes also used off label as anti-aging therapy and for athletic performance or for bodybuilding. This latter use is illegal in the United States.

Diagnosis code ICD-10-CM E23.0 (hypopituitarism) can be used either for a serious conditions resulting in lack of growth hormone from pituitary disease or absence or a pituitary gland, in association with several developmental syndromes or in an attempt to obtain coverage for human growth hormone used for anti-aging therapy, athletic performance or body building.

Currently, GN74 restricts growth hormone (HGH) use to children "until adult height as determined by bone age is achieved." It also specifies the conditions under which E23.0 is above or below the funding line. As a result, use in adults with FDA approved HGH indications such as pituitary malformation, post-surgical pan hypopituitary dysfunction, or HIV cachexia is not covered under OHP, and some other potentially funded indications related to pediatric-onset endocrine or developmental syndromes are not covered after adult bone age is achieved.

In addition, during OHA's waiver renewal process, an issue was raised about coverage of HGH in an adolescent with closed growth plates who had Prader-Willi syndrome, a genetic multisystem disorder characterized during infancy by lethargy, hypotonia, a weak suck and feeding difficulties with poor weight gain and growth and other hormone deficiency. Treatment of Prader-Willi syndrome in children, as well as persons who have obtained adult height, is an FDA approved indication for certain formulations of HGH.

Currently, congenital pediatric short stature is expressly not covered as the ICD-10-CM code for this condition (E34.3 family) is on line 652 ENDOCRINE AND METABOLIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY. However, this is another FDA approved indication for certain formulations of HGH.

Current Prioritized List status

GUIDELINE NOTE 74, GROWTH HORMONE TREATMENT

Lines 40,386,470,652

Treatment with growth hormone should continue only until adult height as determined by bone age is achieved. ICD-10-CM E23.0 (Hypopituitarism) is included on Lines 40 and 386 for conditions other than adult human growth hormone deficiency. ICD-10-CM E23.0 is included on Line 652 only for adult human growth hormone deficiency.

The current lines referenced in GN74 are 40 PANHYPOPITUITARISM, IATROGENIC AND OTHER PITUITARY DISORDERS, 386 PITUITARY DWARFISM, 470 GONADAL DYSFUNCTION, MENOPAUSAL MANAGEMENT and 652 ENDOCRINE AND METABOLIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

Expert guideline (Adults)

1) **Yuen 2019,** AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND AMERICAN COLLEGE OF ENDOCRINOLOGY GUIDELINES FOR MANAGEMENT OF GROWTH HORMONE DEFICIENCY IN ADULTS
    a. Adult GHD is a well-defined clinical entity characterized by decreased lean body mass and increased fat mass, dyslipidemia, cardiac dysfunction, decreased fibrinolysis and premature atherosclerosis, decreased muscle strength and exercise capacity, decreased bone mineral density (BMD), increased insulin resistance, and impaired QoL
    b. It is recommended that adults with childhood onset growth hormone deficiency caused by structural pituitary or brain tumors be followed up closely during transition as these patients tend to have lower bone mineral density, impaired bone microarchitecture, and more adverse body composition abnormalities and cardiovascular risk markers than those with adult onset growth hormone deficiency (Grade A; BEL 1).
    c. In the U.S., off-label distribution or marketing of GH for the enhancement of athletic performance or to treat aging or aging-related conditions is illegal and punishable by imprisonment. Under no circumstances should rhGH be prescribed for sports or for “anti-aging” purposes (Grade A; BEL 1).

Other payer policies

1) Premara BCBS 2022
- **a.** Growth hormone* may be considered medically necessary in the treatment of adults who meet ALL criteria for the conditions listed below:
    - **i.** AIDS wasting syndrome
    - **ii.** Severe growth hormone deficiency
        - **1.** Adult growth deficiency must be confirmed by a negative response to a growth hormone stimulation test (eg, serum GH levels of <5 ng/ml on stimulation testing with either of the following: glucagon or insulin). OR

2. Growth hormone deficiency may be assumed without a stimulation test if patient has had the pituitary removed or destroyed or has had panhypopituitarism since birth.
AND
3. Growth hormone therapy is prescribed by or in consultation with an endocrinologist

iii. Short bowel syndrome

b. Growth hormone is considered not medically necessary in the treatment of idiopathic short stature without growth hormone deficiency.

2) Cigna 2022

a. Growth Hormone Deficiency in an Adult or Transition Adolescent. Approve for 1 year if the individual meets the following criteria (A, B, C, and D):

A) The endocrinologist must certify that somatropin is not being prescribed for anti-aging therapy or to enhance athletic ability or for body building; AND

B) Individual must have a diagnosis of growth hormone deficiency that is one of the following (i or ii): [documentation required for all elements]

i. Childhood onset; OR

ii. Adult onset that results from one of the following: growth hormone deficiency alone or multiple hormone deficiencies (hypopituitarism) resulting from pituitary disease, hypothalamic disease, pituitary surgery, cranial radiation therapy, tumor treatment, traumatic brain injury, or subarachnoid hemorrhage; AND

C) Individual meets one of the following criteria (i, ii, or iii):

i. Individual (adult or transition adolescent) has known mutations, embryopathic lesions, congenital or genetic defects, or structural hypothalamic-pituitary defects; [documentation required] OR

ii. Individual meets the following criteria (a, b, and c):

a) Individual (adult onset or transition adolescent) has three or more of the following pituitary hormone deficiencies: Adrenocorticotropic hormone, thyroid-stimulation hormone, gonadotropin deficiency (luteinizing hormone and/or follicle stimulating hormone deficiency are counted as one deficiency), and prolactin [documentation required]; AND

b) The age and gender adjusted serum insulin-like growth factor-1 is below the lower limit of the normal reference range for the reporting laboratory [documentation required]; AND

Other causes of low serum insulin-like growth factor-1 have been excluded (e.g., malnutrition, prolonged fasting, poorly controlled diabetes mellitus, hypothyroidism, hepatic insufficiency, oral estrogen therapy); OR

Individual meets one of the following (a or b):

a) Adult. Individual has had a negative response to one of the following standard growth hormone stimulation tests (1, 2, 3, 4, 5, or 6) [documentation required for all elements]: Note: If the individual has had a previous trial of an arginine alone test with a peak response of ≤ 0.4 mcg/L, this would meet the criteria for a negative response to a growth hormone stimulation test.

(1) Insulin tolerance test (obtaining at least 3 growth hormone levels in at least a 60 minute timeframe [not including a level at timeframe zero], with adequate hypoglycemia being achieved) with peak response ≤ 5.0 mcg/L; OR
(2) Glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with peak response ≤ 3.0 mcg/L AND the individual's body mass index (BMI) is < 25 kg/m2; OR
(3) Glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response ≤ 3.0 mcg/L AND the individual's BMI is ≥ 25 kg/m2 and ≤ 30 kg/m2 with, according to the prescriber, a high pretest probability of growth hormone deficiency; OR
(4) Glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response ≤ 1.0 mcg/L AND the individual's BMI is ≥ 25 kg/m2 and ≤ 30 kg/m2 with, according to the prescriber, a low pretest probability of growth hormone deficiency; OR
(5) Glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with peak response ≤ 1.0 mcg/L AND the individual's BMI is > 30 kg/m2; OR
(6) Macrilen (macimorelin oral solution) test (obtaining at least 4 growth hormone levels in at least a 90 minute timeframe [not including a level at timeframe zero]) with peak responses < 2.8 ng/mL (2.8 mcg/L) AND the individual's BMI is ≤ 40 kg/m2. Note: The following formula can be used to calculate BMI: BMI equals body weight in kg divided by height meters squared (m2) [i.e., BMI = kg/m2]; OR

HERC staff summary:
Human growth hormone treatment is indicated in adults with childhood onset growth hormone deficiency caused by structural pituitary damage, brain tumors or clinically significant pituitary dysfunction when medically appropriate based on expert guidelines. For people under age 21, the Early and Periodic Screening, Diagnosis and Treatment Program as well as recent changes to HERC's statement of intent 4 requiring coverage of services which would benefit a child in terms of growth, development and ability to attend school.

HERC staff recommends modifying the current guideline to clearly exclude use of these agents for anti-aging therapy, to enhance athletic ability or for body building, but to allow limited appropriate use in adults. In addition, the guideline would require consultation with an endocrinologist, as well as lab or historical evidence of lack of growth hormone.

HERC staff recommendations:

1) Remove GN74 from line 470 GONADAL DYSFUNCTION, MENOPAUSAL MANAGEMENT
2) Modify GN74 as shown below

GUIDELINE NOTE 74, GROWTH HORMONE TREATMENT

Lines 40,386,~~470,~~652

~~Treatment with growth hormone should continue only until adult height as determined by bone age is achieved. ICD-10-CM E23.0 (Hypopituitarism) is included on Lines 40 and 386 for conditions other than adult human growth hormone deficiency. ICD-10-CM E23.0 is included on Line 652 only for adult human growth hormone deficiency.~~

Treatment with growth hormone for ICD-10-CM E23.0 (Hypopituitarism) is included on Lines 40 and 386 for adults when

1 Prescribed by or in consultation with an endocrinologist; AND
2 Either
   i. Growth hormone deficiency is confirmed by a negative response to a growth hormone stimulation test (eg, serum GH levels of <5 ng/ml on stimulation testing with either of the following: glucagon or insulin); OR
   ii. patient has had the pituitary removed or destroyed or has had panhypopituitarism since birth; AND
3 The prescriber certifies that the growth hormone is not being prescribed for anti-aging therapy or to enhance athletic ability or body building

ICD-10-CM E23.0 is included on Line 652 only for adult human growth hormone deficiency that does not meet the above criteria.

Treatment of children and adolescents with growth hormone (for any indication) must be evaluated for medical appropriateness and medical necessity on a case-by-case basis. Therapy must be initiated by and continued in consultation with a pediatric endocrinologist.

FDA approved indications for various HGH agents

GENOTROPIN (somatropin) for injection, for subcutaneous use

Pediatric: Treatment of children with growth failure due to growth hormone deficiency, Prader-Willi syndrome, Small for Gestational Age, Turner syndrome, and Idiopathic Short Stature.

Adult: Treatment of adults with either adult onset or childhood onset GHD

HUMATROPE (somatropin) for injection, for subcutaneous use

Pediatric: Growth failure due to inadequate secretion of endogenous growth hormone; short stature associated with Turner syndrome; Idiopathic Short Stature, height standard deviation score <-2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range; short stature or growth failure in short stature homeobox-containing gene deficiency; short stature born small for gestational age with no catch-up growth by 2 years to 4 years of age.

Adult: Replacement of endogenous growth hormone in adults with growth hormone deficiency.

NORDITROPIN (somatropin) injection, for subcutaneous use

Pediatric: Treatment of pediatric patients with growth failure due to inadequate secretion of endogenous growth hormone, short stature associated with Noonan syndrome, short stature associated with Turner syndrome, short stature born small for gestational age with no catch-up growth by age 2 to 4 years, Idiopathic Short Stature, and growth failure due to Prader-Willi Syndrome.

Adult: Replacement of endogenous growth hormone in adults with growth hormone deficiency.

NUTROPIN (somatropin) injection, for subcutaneous use

Pediatric: Treatment of children with growth failure due to growth hormone deficiency, idiopathic short stature, Turner syndrome, and chronic kidney disease up to the time of renal transplantation.

Adult: Treatment of adults with either childhood-onset or adult-onset growth hormone deficiency.

OMNITROPE (somatropin) injection, for subcutaneous use

Pediatric: Treatment of children with growth failure due to growth hormone deficiency, Prader-Willi Syndrome, Small for Gestational Age, Turner syndrome, and Idiopathic Short Stature.

Adult: Treatment of adults with either adult onset or childhood onset growth hormone deficiency.

SAIZEN (somatropin) for injection, for subcutaneous use

Pediatric: Treatment of children with growth failure due to growth hormone deficiency.

Adult: Treatment of adults with either adult onset or childhood onset growth hormone deficiency.

SEROSTIM (somatropin) for injection, for subcutaneous use

Pediatric and Adult: Treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance.

SKYTROFA (lonapegsomatropin-tcgd) for injection, for subcutaneous use

Pediatric: treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone.

Adult: N/A

ZOMACTON (somatropin) for injection, for subcutaneous use

Pediatric: Treatment of pediatric patients with growth failure due to inadequate secretion of endogenous growth hormone, short stature associated with Turner syndrome, idiopathic short stature, short stature or growth failure in short stature homeobox-containing gene deficiency, and short stature born small for gestational age with no catch-up growth by 2 years to 4 years.

Adult: Replacement of endogenous growth hormone in adults with growth hormone deficiency.

ZORBTIVE (somatropin) for injection, for subcutaneous use

Pediatric: N/A

Adult: Treatment of short bowel syndrome in adult patients receiving specialized nutritional support.

ABSTRACT

Objective: The development of these guidelines is sponsored by the American Association of Clinical Endocrinologists (AACE) Board of Directors and American College of Endocrinology (ACE) Board of Trustees and adheres with published AACE protocols for the standardized production of clinical practice guidelines (CPG).

Methods: Recommendations are based on diligent reviews of clinical evidence with transparent incorporation of subjective factors, according to established AACE/ACE guidelines for guidelines protocols.

Results: The Executive Summary of this 2019 updated guideline contains 58 numbered recommendations: 12 are Grade A (21%), 19 are Grade B (33%), 21 are Grade C (36%), and 6 are Grade D (10%). These detailed, evidence-based recommendations allow for nuance-based clinical decision-making that addresses multiple aspects of real-world care of patients. The evidence base presented in the subsequent Appendix provides relevant supporting information for the Executive Summary recommendations. This update contains 357 citations of which 51 (14%) are evidence level (EL) 1 (strong), 168 (47%) are EL 2 (intermediate), 61 (17%) are EL 3 (weak), and 77 (22%) are EL 4 (no clinical evidence).

Conclusion: This CPG is a practical tool that practicing endocrinologists and regulatory bodies can refer to regarding the identification, diagnosis, and treatment of adults and patients transitioning from pediatric to adult-care services with growth hormone deficiency (GHD). It provides guidelines on assessment, screening, diagnostic testing, and treatment recommendations for a range of individuals with various causes of adult GHD. The recommendations emphasize the importance of considering testing patients with a reasonable level of clinical suspicion of GHD using appropriate growth hormone (GH) cut-points for various GH–stimulation tests to accurately diagnose adult GHD, and to exercise caution interpreting serum GH and insulin-like growth factor-1 (IGF-1) levels, as various GH and IGF-1 assays are used to support treatment decisions. The intention to treat often requires sound clinical judgment and careful assessment of the benefits and risks specific to each individual patient. Unapproved uses of GH, long-term safety, and the current status of long-acting GH preparations are also discussed in this document. **(Endocr Pract. 2019;25:1191-1232)**

LAY ABSTRACT

This updated guideline provides evidence-based recommendations regarding the identification, screening, assessment, diagnosis, and treatment for a range of individuals with various causes of adult growth-hormone deficiency (GHD) and patients with childhood-onset GHD transitioning to adult care. The update summarizes the most current knowledge about the accuracy of available GH–stimulation tests, safety of recombinant human GH (rhGH) replacement, unapproved uses of rhGH related to sports and aging, and new developments such as long-acting GH preparations that use a variety of technologies to prolong GH action. Recommendations offer a framework for physicians to manage patients with GHD effectively during transition to adult care and adulthood. Establishing a correct diagnosis is essential before consideration of replacement therapy with rhGH. Since the diagnosis of GHD in adults can be challenging, GH–stimulation tests are recommended based on individual patient circumstances and use of appropriate GH cut-points. Available GH–stimulation tests are discussed regarding variability, accuracy, reproducibility, safety, and contraindications, among other factors. The regimen for starting and maintaining rhGH treatment now uses individualized dose adjustments, which has improved effectiveness and reduced reported side effects, dependent on age, gender, body mass index, and various other individual characteristics. With careful dosing of rhGH replacement, many features of adult GHD are reversible and side effects of therapy can be minimized. Scientific studies have consistently shown rhGH therapy to be beneficial for adults with GHD, including improvements in body composition and quality of life, and have demonstrated the safety of short- and long-term rhGH replacement.

Abbreviations:
AACE = American Association of Clinical Endocrinologists; **ACE** = American College of Endocrinology; **AHSG** = alpha-2-HS-glycoprotein; **AO-GHD** = adult-onset growth hormone deficiency; **ARG** = arginine; **BEL** = best evidence level; **BMD** = bone mineral density; **BMI** = body mass index; **CI** = confidence interval; **CO-GHD** = childhood-onset growth hormone deficiency; **CPG** = clinical practice guideline; **CRP** = C-reactive protein; **DM** = diabetes mellitus; **DXA** = dual-energy X-ray absorptiometry; **EL** = evidence level; **FDA** = Food and Drug Administration; **FD-GST** = fixed-dose glucagon stimulation test; **GeNeSIS** = Genetics and Neuroendocrinology of Short Stature International Study; **GH** = growth hormone; **GHD** = growth hormone deficiency; **GHRH** = growth hormone–releasing hormone; **GST** = glucagon stimulation test; **HDL** = high-density lipoprotein; **HypoCCS** = Hypopituitary Control and Complications Study; **IGF-1** = insulin-like growth factor-1; **IGFBP** = insulin-like growth factor–binding protein; **IGHD** = isolated growth hormone deficiency; **ITT** = insulin tolerance test; **KIMS** = Kabi International Metabolic Surveillance; **LAGH** = long-acting growth hormone; **LDL** = low-density lipoprotein; **LIF** = leukemia inhibitory factor; **MPHD** = multiple pituitary hormone deficiencies; **MRI** = magnetic resonance imaging; **P-III-NP** = procollagen

Evidence Based Chronic Disease Self Management Programs

Question: Should evidence based chronic disease self management programs be added for coverage?

Question source: Community Integrated Network of Oregon

Issue: The Community Integrated Network of Oregon requested that the HERC review the evidence supporting various chronic disease self management programs developed by the Self-Management Resource Center (SMRC). These are programs that have significant research and data that verify their effectiveness and for which OHA, local public health and AAA/APD partners have supported training for program leaders over many years across the state.

The HERC has previously added coverage of the Diabetes Prevention Program as well as fall prevention programs. These programs were shown to have evidence of effectiveness found in a MED review and in a systematic review for the Community Preventive Services Task Force.

Requested programs for review:
- Chronic Disease Self-Management Program (CDSMP or Living Well with Chronic Conditions)
- Tomando Control de su Salud (Spanish CDSMP)
- Chronic Pain Self-Management Program (CPSMP)
- Programa de Manejo Personal del Dolor Crónico (Spanish CPSMP)
- HIV: Positive Self-Management Program (PSMP)
- Cancer: Thriving and Surviving
- Living Well in the Community (formerly known as Living Well with a Disability)

From the CDC:
There is strong evidence from peer-reviewed publications and program evaluations that participation in CDSMP workshops can improve physical and psychosocial outcomes and quality of life for people with chronic health conditions.

Current Prioritized List status

CPT Code	Code Description	Current Placement
98961	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 2-4 patients	1 PREGNANCY 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS 8 TYPE 1 DIABETES MELLITUS 27 TYPE 2 DIABETES MELLITUS
98962	5-8 patients	1,3,8,27
HCPCS code	**Code Description**	**Current Placement**
G0108	Diabetes outpatient self-management training services, individual, per 30 minutes	1,8,27
G0109	group session (2 or more)	1,8,27
S9445	Patient education, not otherwise classified, non-physician provider, individual, per session	ANCILLARY PROCEDURES
S9446	Patient education, not otherwise classified, non-physician provider, group, per session	ANCILLARY PROCEDURES
S9449	Weight management classes, non-physician provider, per session	EXCLUDED FILE (TRAVEL VACCINES ETC.)
S9451	Exercise classes, non-physician provider, per session	3 PREVENTION SERVICES WITH EVIDENCE 401 CONDITIONS OF THE BACK AND SPINE
S9452	Nutrition classes, non-physician provider, per session	EXCLUDED FILE (TRAVEL VACCINES ETC.)
S9454	Stress management classes, non-physician provider, per session	EXCLUDED FILE (TRAVEL VACCINES ETC.)

STATEMENT OF INTENT 5: TREATMENT OF CHRONIC PAIN

It is the intent of the Commission that covered chronic pain conditions be treated in a multidisciplinary fashion, with a focus on active therapies, improving function, and demedicalizing the condition. Care should include education on sleep, nutrition, stress reduction, mood, exercise, and knowledge of pain. All providers seeing chronic pain patients should be trained in pain science (e.g. a contemporary understanding of the central and peripheral nervous system in chronic pain), motivational interviewing, culturally sensitive care, and trauma-informed care. Care should be provided as outlined in the Oregon Pain Management Commission pain management module: https://www.oregon.gov/oha/HPA/DSI-PMC/Pages/module.aspx.

GUIDELINE NOTE 106, PREVENTIVE SERVICES

Lines 3,622

Included on Line 3 are the following preventive services:

A) US Preventive Services Task Force (USPSTF) "A" and "B" Recommendations in effect and issued prior to January 1, 2021.

1) http://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/
    a) Treatment of falls prevention with exercise interventions is included on Line 292.
2) USPSTF "D" recommendations are not included on this line or any other line of the Prioritized List.

B) American Academy of Pediatrics (AAP) Bright Futures Guidelines:
1) http://brightfutures.aap.org. Periodicity schedule available at http://www.aap.org/en-us/professional-resources/practice-support/Periodicity/Periodicity Schedule_FINAL.pdf.
    a) Bright Futures is the periodicity schedule for screening for EPSDT for the Oregon Health Plan.
2) Screening for lead levels is defined as blood lead level testing and is indicated for Medicaid populations at 12 and 24 months. In addition, blood lead level screening of any child between ages 24 and 72 months with no record of a previous blood lead screening test is indicated.

C) Health Resources **and Services Administration (HRSA) Women's Preventive Services-Required Health Plan Coverage Guidelines a**s updated by HRSA in December 2019. Available at https://www.hrsa.gov/womens-guidelines-2019 as of September 4, 2020.

D) Immunizations as recommended by the Advisory Committee on Immunization Practices (ACIP): http://www.cdc.gov/vaccines/schedules/hcp/index.html or approved for the Oregon Immunization Program: https://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/Documents/DMAPvactable.pdf
1) COVID-19 vaccines are intended to be included on this line even if the specific administration code(s) do not yet appear on the line when the vaccine has both 1) FDA approval or FDA emergency use authorization (EUA) and 2) ACIP recommendation.

Colorectal cancer screening is included on Line 3 for average-risk adults aged 45 to 75, using one of the following screening programs:

A) Colonoscopy every 10 years
B) Flexible sigmoidoscopy every 5 years
C) Fecal immunochemical test (FIT) every year
D) Guaiac-based fecal occult blood test (gFOBT) every year

CT colonography (CPT 74263), FIT-DNA (CPT 81528) and mSEPT9 (HCPCS G0327) are included on Line 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS.

Colorectal cancer screening for average-risk adults aged 76 to 85 is covered after informed decision making between patients and clinicians which includes consideration of the patient's overall health, prior screening history, and preferences.

Supervised evidence-based exercise programs for fall prevention for persons aged 65 or older OR younger patients who are at increased risk of falls are included on Line 3 using CPT 98961 or 98962 or HCPCS S9451. HCPCS S9451 is only included on Line 3 for the provision of supervised exercise therapy for fall prevention. Programs should be culturally tailored/culturally appropriate when feasible.

Note: CPT 96110 (Developmental screening (e.g., developmental milestone survey, speech and language delay screen), with scoring and documentation, per standardized instrument) can be billed in addition to other CPT codes, such as evaluation and management (E&M) codes or preventive visit codes.

The development of this guideline note was informed by a HERC coverage guidance. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx

GUIDELINE NOTE 179, DIABETES PREVENTION PROGRAM

Line 3

Prediabetes (R73.03) and personal history of gestational diabetes (Z86.32) are included on this line only for the Diabetes Prevention Program (DPP). The only programs included are CDC-recognized lifestyle change programs for DPP.

To be eligible for referral to a CDC-recognized lifestyle change program, patients must meet ALL of the following requirements (A-E):

A) Be at least 18 years old
B) Be overweight (body mass index ≥25; ≥23 if Asian; BMI percentile ≥85th percentile for 18-19 years old)
C) Have no current diagnosis of type 1 or type 2 diabetes
D) Not have end-stage renal disease
E) Have a blood test result in the prediabetes range within the past year:
    1) Hemoglobin A1C: 5.7%–6.4% or
    2) Fasting plasma glucose: 100–125 mg/dL or
    3) Two-hour plasma glucose (after a 75 gm glucose load): 140–199 mg/dL or
    4) Have a previous diagnosis of gestational diabetes

Evidence Based Chronic Disease Self Management Programs

Evidence

Chronic Disease Self Management program

Listed as a recognized program by the CDC for arthritis, diabetes, lung, and heart disease management covering physical activity, appropriate use of medications, effective communication. Tomando Control De su Salud is recognized by the CDC as the Spanish version of the CDSM program. The Chronic Pain Self-Management Program is CDC recognized for people with primary or secondary diagnosis of chronic pain.

1) **Brady 2013,** A Meta-Analysis of Health Status, Health Behaviors, and Health Care Utilization Outcomes of the Chronic Disease Self-Management Program
    a. N=23 studies (8,688 participants)
        i. RCTs and longitudinal studies
    b. Of the 4 health behaviors studied among the small English-speaking groups, 3 showed significant small or moderate effects at 4 to 6 months: aerobic exercise (ES, 0.12); cognitive symptom management (ES, 0.26), and communication with physician (ES, 0.26). The improvements in aerobic exercise and cognitive symptom management remained significant at 9 to 12 months. Stretching/strengthening exercise showed no significant effects at 4 to 6 months but did show a small significant effect at 9 to 12 months
    c. We observed moderate significant effects for all psychological outcomes at 4 to 6 months and at 9 to 12 months; ESs ranged from 0.45 to −0.28. The strength of effects for depression and health distress were similar at both follow-up points. Whereas the effects for overall self-efficacy declined from the short-term to the long-term, they increased at 9 to 12 months for both self-efficacy for disease management and self-efficacy for management of other symptoms.
    d. Changes in physical health outcomes were less consistent than changes in psychological outcomes. Energy, fatigue, and self-rated health showed small but significant improvements at 4 to 6 months but not at 9 to 12 months. Pain and shortness of breath did not change at 4 to 6 months but showed small significant improvements at 9 to 12 months. Functional disability did not change at either follow-up point. The small significant improvements in social role limitations at 4 to 6 months remained at 9 to 12 months.
    e. The only significant change in health care utilization outcomes was a small improvement in the number of hospitalization days or nights at 4 to 6 months, but this improvement was not significant at 9 to 12 months.
2) **Franek 2013**, Ontario Health Technology Assessment Series evidence review of Stanford Chronic Disease Self-Management Program
    a. N=10 RCTs (6074 patients)
    b. 6 month or less of follow up
    c. Health status outcomes: There was a small, statistically significant improvement in favor of CDSMP across most health status measures, including pain, disability, fatigue, depression, health distress, and self-rated health (GRADE quality low). There was no significant difference between modalities for dyspnea (GRADE quality very low). There was significant improvement in health-related quality of life according to the EuroQol 5-D in favor of CDSMP, but inconsistent findings across other quality-of-life measures.
    d. Healthy behavior outcomes: There was a small, statistically significant improvement in favor of CDSMP across all healthy behaviors, including aerobic exercise, cognitive

symptom management, and communication with health care professionals (GRADE quality low).

e. Self-efficacy: There was a small, statistically significant improvement in self-efficacy in favor of CDSMP (GRADE quality low).
f. Health care utilization outcomes: There were no statistically significant differences between modalities with respect to visits with general practitioners, visits to the emergency department, days in hospital, or hospitalizations (GRADE quality very low).
g. The Stanford CDSMP led to statistically significant, albeit clinically minimal, short-term improvements across a number of health status measures (including some measures of health-related quality of life), healthy behaviors, and self-efficacy compared to usual care. However, there was no evidence to suggest that the CDSMP improved health care utilization. More research is needed to explore longer-term outcomes, the impact of self-management on clinical outcomes, and to better identify responders and non-responders.

3) **CDC 2011**, Meta-analyses of Stanford arthritis and chronic disease self-management programs
   a. Note: ES of less than ± 0.20 were considered small, ± 0.20–0.80 were considered medium, and greater than ± 0.80 were considered large.
   b. Chronic disease self-management program (CDSMP)
      i. N=23 studies (8,688 participants; 2,902 RCTs and 5,779 in longitudinal studies)
      ii. Outcomes
         1. General self-efficacy: ES = 0.345 (4-6 months) and ES = 0.204 (9-12 months)
         2. Health distress: ES = -0.282 (4-6 months) and ES = -0.227 (9-12 months)
         3. Energy and fatigue showed small but significant improvements at 4–6 months (ES = 0.158 and ES = -0.138, respectively) but they did not persist at 9–12 months.
         4. Functional disability showed no significant changes in overall effects in the analyses at 4–6 months and 9–12 months.
         5. Health Care Utilization: Changes were minimal. Three of the four variables measured showed no significant effect sizes at 4–6 months or 9–12 months. There was a small but significant change in the fourth measure, days in the hospital, at 4–6 months (ES = -0.088) that did not persist at 9–12 months
   c. Conclusions: The findings suggested that CDSMP contribute to improvements in psychological health status, self-efficacy, and select health behaviors and that many of those improvements are maintained over 12 months. While the effects are modest, they have great public health significance when the cumulative impact of small changes across a large population is considered.
   d. Policy recommendations based on review
      i. *Invest public and private resources (financial and human capital) to support wide-scale delivery of CDSMP to reach large population groups with chronic disease. Appropriate financing systems need to be identified.*
      ii. *Support wide-scale implementation of CDSMP to produce meaningful public health impact. Service delivery systems, in both community and health care settings, should consider adding these ready-to implement programs to their menu of services.*

HIV self-management programs

1) **Nkhoma 2018**, systematic review of effect of self-management education programs on people living with HIV/AIDS
    a) N=19 studies (2189 participants)
        i) 17 RCTs, 2 quasi-experimental designs
    b) Outcomes for physical symptoms were reported in 13 studies with 6 studies reporting positive effect. The quality of evidence was moderate for pain outcomes. For physical symptoms, one study was rated as moderate; the rest were rated as low n = 8 and very low n = 4 quality.
    c) Three studies reported data on pain severity as a primary outcome, and 2 studies reported data on pain interference as a secondary outcome. Only one study found significant differences on pain severity and interference. Although the quality of evidence in studies that assessed pain outcomes was downgraded because of risk of bias following lack of blinding, the overall quality of evidence was moderate.
    d) Symptom severity and frequency was reported in 8 studies. Three of the 8 studies reported significant decrease in symptom severity and frequency
    e) Quality of life was reported in 9 studies. Four studies reported statistically significant effects of the intervention on some subscales of quality of life
    f) Conclusions: There is some evidence to suggest that self-management interventions delivered either online, face-to-face, or group-based consisting of booklet, leaflet, or manuals are effective in improving pain and physical symptoms
2) **Millard 2013**, systematic review of effect of self-management education programs on people living with HIV/AIDS
    a) N=6 studies (1178 participants)
    b) The review found randomized controlled trials (RCT) evidence sufficient to infer that self-management programs for people living with HIV/AIDS result in short-term improvements in physical, psychosocial, and health knowledge and behavioral outcomes. Statistically significant improvements were reported for intervention participants compared to control participants across most outcomes. There is insufficient evidence to provide conclusions regarding the long-term outcomes of HIV-specific self-management interventions

HERC staff summary

Chronic disease management programs such as the Chronic Disease Self-Management Program have been shown to have small impacts on pain and function. There is no evidence that these programs reduce health care utilization. However, the CDC recommends encouragement of wide-scale implementation of these programs. These programs have the support of OHA and are available in many locations and in culturally appropriate formats in Oregon.

These programs can be paid for by CCOs out of their discretionary funds. To assist in CCOs selecting programs to support, HERC staff recommend adopting a new multi-sector intervention regarding chronic disease self-management programs.

HERC staff recommendation:

1) Option 1: recommend to HERC that EBGS take up this topic as a multi-sector intervention review
2) Option 2: Adopt a new multi-sector intervention statement as shown below

MULTISECTOR INTERVENTION STATEMENT XX: CHRONIC DISEASE SELF-MANAGEMENT PROGRAMS

Limited evidence supports the following CDC recommended interventions:

- Chronic Disease Self-Management Program (CDSMP)
- Tomando Control de su Salud (Spanish CDSMP)
- Chronic Pain Self-Management Program (CPSMP)
- Programa de Manejo Personal del Dolor Crónico (Spanish CPSMP)
- HIV: Positive Self-Management Program (PSMP)
- Cancer: Thriving and Surviving
- Living Well in the Community (formerly known as Living Well with a Disability)

Community Integrated Network of Oregon

Health Evidence Review Commission
Health Policy & Analytics Division
Delivery Systems Innovation
500 Summer St. NE, E-65
Salem OR 97301

September 2, 2022

To Dr. Ariel Smits and the Health Evidence Review Commission Members,

This letter is a formal request to the Health Evidence Review Commission (HERC) to consider Oregon Health Plan (OHP) coverage for a suite of evidence-based chronic disease self-management programs developed by the Self-Management Resource Center (SMRC). The evidence-based Chronic Disease Self-Management Education (CDSME) programs included in this consideration request originated at Stanford University in 1993 and transitioned to the SMRC in 2017. The programmatic scope of this request includes:

- Chronic Disease Self-Management Program (CDSMP or Living Well with Chronic Conditions)
- Tomando Control de su Salud (Spanish CDSMP)
- Chronic Pain Self-Management Program (CPSMP)
- Programa de Manejo Personal del Dolor Crónico (Spanish CPSMP)
- HIV: Positive Self-Management Program (PSMP)
- Cancer: Thriving and Surviving
- Living Well in the Community (formerly known as Living Well with a Disability)

This request is made by the Community Integrated Network of Oregon (CINO), a network of diverse partners focused on building the statewide infrastructure to deliver and sustain evidence-based health education programs and interventions. The goals of CINO are to increase access to evidence-based health education, implement closed loop referral systems, and establish billing infrastructures. These partners are invested and engaged in implementing the existing Medicaid coverage for the National Diabetes Prevention Program, Falls Prevention Programs, and Diabetes Self-Management Program and currently deliver CDSME programs as grant funding allows. Adding these additional CDSME programs to Oregon's Prioritized List of Health Services will increase capacity for service delivery and improve access for a broader range of patients who will benefit from services to engage them in improving their self-management skills.

CINO focuses on programs with national accreditation or recognition from bodies such as the Center for Disease Control and Prevention (CDC), Centers for Medicare and Medicaid Services (CMS), Evidence-Based Leadership Council, Administration for Community Living (ACL), and Association of Diabetes Care and Education Specialists (ADCES). Evidence-based CDSME programs provide education and tools to help patients better manage their chronic conditions and are a critical element of preventative healthcare to avoid or delay complications from chronic conditions.

This letter contains the relevant literature and research for the requested evidence based CDSME programs linked to HERC's principles for coverage guidance and consideration. The Health Policy Institute of Ohio's Guide to Evidence-based Prevention provides an additional lens for assessing the evidence below and this consideration for coverage request. CINO would also like to highlight:

- Relevant literature shows improved measurements related to behavior change and self-reported patient self-management of their chronic conditions. CDSME programs are shorter in length compared to more rigorous lifestyle change interventions, such as the yearlong National Diabetes Prevention Program, which means the clinical and outcomes data may not show a significant improvement within the intervention's timeframe.
- There is not one single research study or meta-analysis that captures the full impact of CDSMEs. Instead, we have compiled multiple studies of various scale that demonstrate the impact of CDSME across many topics and the related curriculums.
- The participants that enroll in CDSME have a variety of one or more chronic conditions, which may present a challenge for assessing clinical outcomes grouped by chronic conditions and program delivery cohorts.

HERC has listed the specific principles that are considered when reviewing a policy for OHP coverage. The evidence and literature below summarize how CDSME programs fit these principles.

Summary of Literature Findings and Justification for Coverage

Represents an important uncertainty with regard to effectiveness or harms

Behavior Change Complexity and Challenges in Chronic Care Management

The Chronic Disease Self-Management Program (CDSMP) was developed under the assumption that individuals living with chronic diseases experience similar self-management and disease-related challenges; therefore, the program is designed such that effective strategies should work across various conditions (Hevey, et al., 2018). The general goal is to "enhance self-efficacy managing their health, illness symptoms, and health care utilization" (Hevey, et al., 2018, p. 3). This program utilizes concepts pulled from Bandura's Self-Efficacy Theory, which proposes that an individual's confidence in achieving a behavior predicts successful performance of the behavior. As confidence builds, behavioral goals can become more aligned with recommended preventative or management behaviors. Initially, Lorig et al. (1999) observed several improvements in CDSMP participants including increase in weekly minutes of exercise, frequency of cognitive symptom management, communication with physicians, health distress, and fatigue after 6-months. These results were replicated outside of a clinical setting in 2001, thus proving their relevance in a real-world setting (Lorig, Sobel, & Ritter 2001).

A meta-analysis by Brady et al. provided a quantitative synthesis of 23 studies evaluating CDSMP and found that participants experienced significant improvements in self-efficacy, health distress, social limitations, and cognitive symptoms. They observed statistically significant increases in aerobic exercise, cognitive symptom management, and communication with their physicians after 4-6 month follow up, while stretching/strengthening exercise improved after 9-12 months (Brady, et al., 2013). When reviewing the methods of program delivery, they found small-group delivery demonstrated consistent and sustained improvement in self-efficacy (Brady, et al., 2013). Rural and remote program delivery using telemedicine is also effective with statistically significant improvements in self-efficacy, health behavior, communication with physicians, and health distress (Jaglal, et al., 2013).

Ory et al. (2013) explicitly studied how CDSMP can facilitate Triple Aim goals (better health, better health care, and better value). Significant improvements were observed for all six "better health" outcome variables from baseline to 6- and 12-month follow up, which included self-assessed health status, fatigue, pain, depression, unhealthy physical days, and unhealthy mental health days. Significant improvements were also observed for communication with physician scores, health literacy, and

medication adherence (Ory, et al., 2013). The majority of CDSMP health outcomes were sustained and often strengthened after 12 months.

The SMRC suite of programs includes programming specifically developed with a few key populations in mind, these have been proven effective as well.

- Tomando Control de su Salud, the Spanish-language CDSMP curriculum, demonstrated significant improvements in self-efficacy to manage disease, perceived social/role activities limitations, time spent walking, and time spent performing other aerobic activities (Brady, 2013; Melchior, 2013; Peñarrieta de Córdova, 2017). This has extremely important implications because it indicates that a community-based implementation of CDSME programming has the potential to improve health outcomes for a diverse, Spanish-speaking, older adult population. (Melchior et al., 2013).
- The Positive Self-Management Program (PSMP) is tailored for people living with HIV/AIDS. A systematic review found sufficient evidence supporting short-term improvements in pain severity, health knowledge, and behavioral outcomes (Millard, 2013; Gifford, 1999). A qualitative analysis of PSMP found that community-based, peer-led interventions can have a positive effect on participants and can help facilitate symptom management due to relationship and network development (Webel & Holzemer, 2009). This mentorship helped participants effectively learn by example and shared experience.
- A randomized trial evaluating the effectiveness of Cancer Thriving and Surviving found significant improvements in the following outcomes: provider communication, depression, energy, sleep, and stress-related problems (Risendal, et al., 2014).
- The Living Well in the Community program was developed to support individuals living with disabilities to manage their health and has demonstrated improvements in health-related quality of life and reduced health care utilization among participants in a randomized control trial (Ravesloot, PhD, et al., 2016).

Represents high costs or significant economic impact, a significant burden of disease or health problem, and is of high public interest

It is widely known that chronic disease is the leading contributor to the nation's annual health care costs (CDC, 2021). In 2020, it was reported that more than 86% of total health care costs in the United States were attributable to the treatment of chronic illnesses (Holman, 2020). It is estimated that by 2030, one in five Americans will be 65 years old or older and the number of Americans living with chronic conditions is projected to increase by 37% (Ahn, et al., 2013). Additionally, the prevalence of multiple chronic conditions among people 65 years and older is increasing with a reported 60-75% of older adults having at least two chronic conditions, many of which are preventable (Basu, et al., 2015).

It is vital that we identify and utilize existing cost-effective strategies for preventing and managing chronic disease. Due to the nature of CDSME, evaluation of cost-effectiveness has been limited; however, there are several key studies demonstrating cost-savings. (Adepoju, 2014; Ahn, 2013; Basu, 2015; Lorig, 1999; Lorig, 2001; Siegel, 2020). In 2001, Lorig et al. found that compared to baseline, CDSMP participants made fewer and shorter visits to physicians/ERs at each follow up period, with a total reduction of 2.5 visits/participant (Lorig, et al., 2001). Several studies found that CDSMP can reduce the odds of hospitalization, prolong time-to-hospitalization, and reduce odds of health care utilization, when compared to usual care (Adepoju, 2014; Hevey, 2018, Ory, 2013). A national study found that there were significant reductions in ER visits (5%) at 6-month and 12-month follow-ups and a 3%

decrease in hospitalizations at 6-month follow up (Ahn, et al., 2013). Additionally, they calculated the total health care costs averted per participant to be approximately $700.

Basu et al. utilized several methodologies to demonstrate the cost-effectiveness of CDSMP including health-related quality of life (HRQOL) and EuroQol 5D (EQ-5D) measures, which were then converted into QALYs. They also calculated the incremental cost-effectiveness ratio (ICER), an economic evaluation method that is used when determining if money is well spent by a health promotion program (Basu, et al., 2015). Significant improvements were found from baseline to 12-months and overall ICER ranges from $31,285-$83,285 per QALYs gained for CDSMP participants, with the median of $50,000/QALYs (Basu, et al., 2015, p. 4)[a]. Ravesloot et al. (2016) evaluated the Living Well with a Disability program and found that there was an overall 6-month cost savings of $3227 (and $723 among a trimmed sample) and programs were able to recover all implementation-related costs within 4 months of program delivery. These findings suggest that CDSMP can be a cost-effective strategy to populations who need it most (e.g., older adults and those with co-morbidities).

The literature suggests the estimated program cost is $350/participant;[b] however, scalability of program delivery is an important factor in lowering costs. One study found that programs with low participation may experience higher than average costs and emphasized the importance of building community partnerships to increase recruitment (Page & Palmer, 2014). Self-management of chronic disease is crucial in cost savings analysis because these interventions often empower individuals to take control of their health and emphasize the importance of proactive care; thus, chronic disease complications may be detected early or prevented outright. Lorig et al. (2001) interestingly found that "[CDSMP] participants, who had a mean of 2.2 chronic conditions and increased disability, did not show deterioration in any other health state variables as one would otherwise expect…neither were there significant increases in number of hospitalizations or days in the hospital".

The conditions covered by CDSME programs represent significant burdens to OHP members. Coverage would have a significant economic impact, based on the data available, through preventative care and lessening the burden of the disease long-term; this will cause savings to the wider healthcare system in the future. As we know, addressing these diseases and underlying concerns is an area of high public interest because a significant portion of the population either has one of these conditions or knows someone who does.

Represents important variation or controversy in implementation or practice

Health equity and social determinants of health (SDOH) should be a priority when determining value and efficacy of programs. It is well known that chronic diseases affect populations of color, rural communities, and other historically underserved communities at a disproportionate rate. There has been a concerted effort to address this which resulted in a national study by Ory et al. (2013) having greater racial/ethnic diversity among participants than had previously been seen in research focused on self-management with 45% of respondents self-identifying as African American, Latino, or other ethnic/racial minority group. CDSMEs take a patient-centered approach to chronic conditions and focus on helping patients make lifestyle changes that can increase self-efficacy and change health behaviors with the support of a community. They can have direct, positive impact on several SDOH thus can decrease health disparities among populations. SMRC programs can be delivered via various modalities, languages and settings, while also incorporating opportunities for authentic cultural responsiveness.

[a] There is not a universally accepted threshold value for ICER, but a range between $50,000-$75,000 per QALY gained is considered acceptable.

[b] Costs typically include licensure costs, trained peer personnel, materials, and space rental costs

These key factors can increase the likelihood of accessibility and inclusion by bringing health care to the community level without sacrificing effectiveness.

Many of the programs are adapted for Spanish-speaking populations (e.g., Tomando Control de su Salud and Programa de Manejo Personal del Dolor Crónico). In addition to Spanish, Oregon partners offer programs in Russian, Cantonese, Mandarin, Vietnamese, and Korean. These programs have also been adapted to meet the specific needs of other target populations such as HIV: Positive Self-Management Program and the Cancer: Thriving and Surviving program. One study in Australia found that CDSMP can be successfully implemented with culturally and linguistically diverse populations (Swerissen, et al., 2006). Having the ability to adapt implementation style can increase accessibility to target populations and moves health care into community settings, which is often a successful strategy for participant engagement.

CDSME programs are often delivered by community-based organizations enabling community connection and building trust between leaders and participants. It is also well known that peer-to-peer models of program delivery are highly effective. A study by Jernigan (2010) utilizing community based participatory research (CBPR) principles adapted the CDSMP curriculum to better support Native populations at a local community health center. They trained trusted community members to be program leaders and made necessary adjustments to better serve the community and increase cultural relevance. Activity levels and social connectedness increased among participants. In fact, Jernigan found that by tailoring the program to be culturally responsive, while also maintaining curriculum fidelity, they were able to retain all their participants during the 6-weeks (Jernigan, 2010). Medical mistrust is very common among communities of color and other historically underserved populations due to blatant historical abuse; a key to the success of this program was word of mouth recruitment throughout the community and delivering the program outside of clinical settings (Jernigan, 2010). This higher-than-average completion rate speaks to the importance of flexibility and adaptability of this program in order to meet the needs of the intended populations.

Rural areas tend to have limited access to health care services, have fewer health care providers in their vicinity, and often struggle with geographic barriers (Towne, Jr., Smith, Ahn, & Ory, 2014). Providing coverage for these programs can increase access and bridge the gap for rural residents. Towne et al. (2014) found that when CDSME programs were offered in rural areas, they had higher completion than urban areas. However, “tailored strategies are needed to increase participant recruitment and retention in rural areas to overcome traditional barriers to health service access” (Towne, Jr., Smith, Ahn, & Ory, 2014).

HERC’s goal is to ensure appropriate medical services coverage to OHP members and approve services that improve the individual health of members while addressing health problems that impact the entire state. CDSME programs have been clearly documented to provide improvements while targeting chronic diseases that impact thousands of Oregonians.

Existing Capacity to Provide Service

While the COVID-19 public health emergency greatly impacted the CDSME delivery infrastructure in Oregon, CINO and its partners are rebuilding and ready to serve Oregon’s diverse Medicaid population. CINO’s statewide infrastructure is designed to support local and regional program delivery partners and we are prepared to meet the increased demand for these programs if coverage is granted. Currently, 12 licensed organizations with 16 implementation sites have maintained through the public health emergency or re-established infrastructure either in-person or virtually. These partners are prepared to

serve Medicaid beneficiaries, communities of color, and other under served communities across the state.

A key data system for CINO and its support programs is the Oregon Compass Self-Management Portal. Comagine Health, one of CINO's co-lead network entities, is the license holder for the Oregon Compass Portal and has access to the participant and workshop data.

Conclusion

CINO believes that CDSME programs have a significant amount of evidence indicating sufficient reasoning for coverage for OHP members related to effectiveness of the intervention to improve self-management of chronic conditions and lower long term healthcare spending. We're grateful to HERC for the opportunity to present the evidence and provide justification for why these programs, which we have found to be critical for self-efficacy and overall health improvement, should be covered in the Oregon Health Plan. We look forward to providing testimony regarding our partners' personal and professional experiences and the impact these programs can have on OHP members and communities.

Sincerely,
The Community Integrated Network of Oregon

Supporting Partner Organizations from CINO's Operations Steering Committee, Sustainability Subcommittee, Health System and Clinical Referral Subcommittee, and Patient Marketing & Engagement Subcommittee, and the Area Agencies on Aging

- CareOregon
- Cascadia Health
- Comagine Health
- Connect Oregon (Unite Us)
- Familias en Acción
- Freedmen's Health
- Legacy Health, National Diabetes Prevention Program
- Lifestyle Medicine Group
- Multnomah County Health Department, Racial and Ethnic Approaches to Community Health (REACH)
- Newport 60+ Activity Center
- Oregon Association of Area Agencies on Aging and Disabilities (Rebecca Miller, Chair), including
    - Clackamas County Social Services
    - Community Action Program East Central Oregon (CAPECO)
    - Community Action Team
    - Community Connection of Northeast Oregon
    - Council on Aging of Central Oregon
    - Douglas County Senior & Veterans Services
    - Harney County Senior & Community Services Center
    - Klamath & Lake Counties Council on Aging
    - Malheur Council on Aging
    - Multnomah County Aging, Disability & Veterans Services
    - NorthWest Senior & Disability Services
    - Oregon Cascades West Council of Governments - Senior & Disability Services
    - Rogue Valley Council of Governments - Senior & Disability Services

  - South Coast Business Employment Corporation Area Agency on Aging
- Oregon Department of Human Service - Aging & People with Disabilities, State Unit on Aging
- Oregon Health & Science University (OHSU)
- OHSU Institute on Development and Disability
- Oregon Office on Disability and Health
- Oregon Primary Care Association
- Oregon Recreation and Park Association
- Oregon Wellness Network
- Oregon State University Extension Services
- Providence St. Joseph, Diabetes & Health Education Services, Oregon Region
- Samaritan Health Services, Health Education Department
- Welld Health

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Chronic Disease Self-Management Programs

Help Your Patients Take Charge

Chronic Disease Self-Management Program (CDSMP)

What is it?

- CDSMP was developed by a team of researchers at Stanford University. It's a self-management education workshop attended by people with a variety of chronic health conditions. It aims to build participants' confidence in managing their health and keep them active and engaged in their lives.
- Participants attend a 2½-hour interactive workshop once a week for 6 weeks to learn problem-solving, decision-making, and other techniques for managing problems common to people with chronic diseases. In a typical workshop, participants set a realistic goal for the upcoming week and develop an action plan for meeting that goal. They report on their progress at the following workshop, and solicit feedback from the group to help address any challenges.
- Participants apply the techniques to concerns such as:
  - Addressing the physical and psychological effects of chronic disease (including fatigue, pain, depression, and frustration)
  - Exercising, getting proper nutrition, and using medications appropriately
  - Communicating effectively with family, friends, and health professionals
- Workshops meet in community settings such as senior centers, churches, and hospitals. They are facilitated by two trained leaders, one or both of whom are nonhealth professionals with a chronic disease. Organizations offering workshops must meet Stanford University licensing requirements.

Who is it for?

- CDSMP is for adults with chronic health conditions such as arthritis, diabetes, heart disease, lung disease, and other ongoing health problems.
- The program may be particularly beneficial for people who have more than one health condition, whose health problems have begun to interfere with their valued life activities, or who have had difficulty following your health recommendations.

What are the benefits?

- There is strong evidence from peer-reviewed publications and program evaluations that participation in CDSMP workshops can improve physical and psychosocial outcomes and quality of life for people with chronic health conditions. Benefits include:
  - Decreased pain and health distress
  - Increased energy and less fatigue
  - Increased physical activity
  - Decreased depression
  - Better communication with physicians
  - Decreased social role limitations
  - Increased confidence in managing chronic disease

Chronic Disease Self-Management Program (CDSMP)

For More Information

- Stanford University Patient Education Research Center
  patienteducation.stanford.edu/programs
- Centers for Disease Control and Prevention
  www.cdc.gov/arthritis/interventions/self_manage.htm
- CDC Executive Summary of ASMP/CDSMP Meta-Analyses
  www.cdc.gov/arthritis/docs/asmp-executive-summary.pdf

Contact

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PREVENTING CHRONIC DISEASE
PUBLIC HEALTH RESEARCH, PRACTICE, AND POLICY

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A Meta-Analysis of Health Status, Health Behaviors, and Health Care Utilization Outcomes of the Chronic Disease Self-Management Program

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PEER REVIEWED

Abstract

Introduction
The Chronic Disease Self-Management Program (CDSMP) is a community-based self-management education program designed to help participants gain confidence (self-efficacy) and skills to better manage their chronic conditions; it has been implemented worldwide. The objective of this meta-analysis was to quantitatively synthesize the results of CDSMP studies conducted in English-speaking countries to determine the program's effects on health behaviors, physical and psychological health status, and health care utilization at 4 to 6 months and 9 to 12 months after baseline.

Methods
We searched 8 electronic databases to identify CDSMP-relevant literature published from January 1, 1999, through September 30, 2009; experts identified additional unpublished studies. We combined the results of all eligible studies to calculate pooled effect sizes. We included 23 studies. Eighteen studies presented data on small English-speaking groups; we conducted 1 meta-analysis on these studies and a separate analysis on results by other delivery modes.

Results
Among health behaviors for small English-speaking groups, aerobic exercise, cognitive symptom management, and communication with physician improved significantly at 4- to 6-month follow-up; aerobic exercise and cognitive symptom management remained significantly improved at 9 to 12 months. Stretching/strengthening exercise improved significantly at 9 to 12 months. All measures of psychological health improved significantly at 4 to 6 months and 9 to 12 months. Energy, fatigue, and self-rated health showed small but significant improvements at 4 to 6 months but not at 9 to 12 months. The only significant change in health care utilization was a small improvement in the number of hospitalization days or nights at 4 to 6 months

Conclusion
Small to moderate improvements in psychological health and selected health behaviors that remain after 12 months suggest that CDSMP delivered in small English-speaking groups produces health benefits for participants and would be a valuable part of comprehensive chronic disease management strategy.

Introduction

The Chronic Disease Self-Management Program (CDSMP) is a 6-week community-based, self-management education program designed to help participants gain the confidence (self-efficacy) and skills to better manage their chronic conditions. It is taught by trained leaders who follow a structured protocol and given to participants who have various chronic conditions (1). Developed at Stanford University, the program has been disseminated throughout the United States and worldwide (1–4). A Spanish-language version (5) and alternative delivery modes, such as Internet-based "virtual" small-group classes (6), are also available.

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Health Quality Ontario
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Self-Management Support Interventions for Persons With Chronic Disease: An Evidence-Based Analysis

J Franek

September 2013

Ontario Health Technology Assessment Series; Vol. 13: No. 9, pp. 1–60, September 2013

Abstract

Background

Self-management support interventions such as the Stanford Chronic Disease Self-Management Program (CDSMP) are becoming more widespread in attempt to help individuals better self-manage chronic disease.

Objective

To systematically assess the clinical effectiveness of self-management support interventions for persons with chronic diseases.

Data Sources

A literature search was performed on January 15, 2012, using OVID MEDLINE, OVID MEDLINE In-Process and Other Non-Indexed Citations, OVID EMBASE, EBSCO Cumulative Index to Nursing & Allied Health Literature (CINAHL), the Wiley Cochrane Library, and the Centre for Reviews and Dissemination database for studies published between January 1, 2000, and January 15, 2012. A January 1, 2000, start date was used because the concept of non–disease-specific/general chronic disease self-management was first published only in 1999. Reference lists were examined for any additional relevant studies not identified through the search.

Review Methods

Randomized controlled trials (RCTs) comparing self-management support interventions for general chronic disease against usual care were included for analysis. Results of RCTs were pooled using a random-effects model with standardized mean difference as the summary statistic.

Results

Ten primary RCTs met the inclusion criteria (n = 6,074). Nine of these evaluated the Stanford CDSMP across various populations; results, therefore, focus on the CDSMP.

- Health status outcomes: There was a small, statistically significant improvement in favour of CDSMP across most health status measures, including pain, disability, fatigue, depression, health distress, and self-rated health (GRADE quality low). There was no significant difference between modalities for dyspnea (GRADE quality very low). There was significant improvement in health-related quality of life according to the EuroQol 5-D in favour of CDSMP, but inconsistent findings across other quality-of-life measures.
- Healthy behaviour outcomes: There was a small, statistically significant improvement in favour of CDSMP across all healthy behaviours, including aerobic exercise, cognitive symptom management, and communication with health care professionals (GRADE quality low).
- Self-efficacy: There was a small, statistically significant improvement in self-efficacy in favour of CDSMP (GRADE quality low).

- Health care utilization outcomes: There were no statistically significant differences between modalities with respect to visits with general practitioners, visits to the emergency department, days in hospital, or hospitalizations (GRADE quality very low).
- All results were measured over the short term (median 6 months of follow-up).

Limitations

Trials generally did not appropriately report data according to intention-to-treat principles. Results therefore reflect "available case analyses," including only those participants whose outcome status was recorded. For this reason, there is high uncertainty around point estimates.

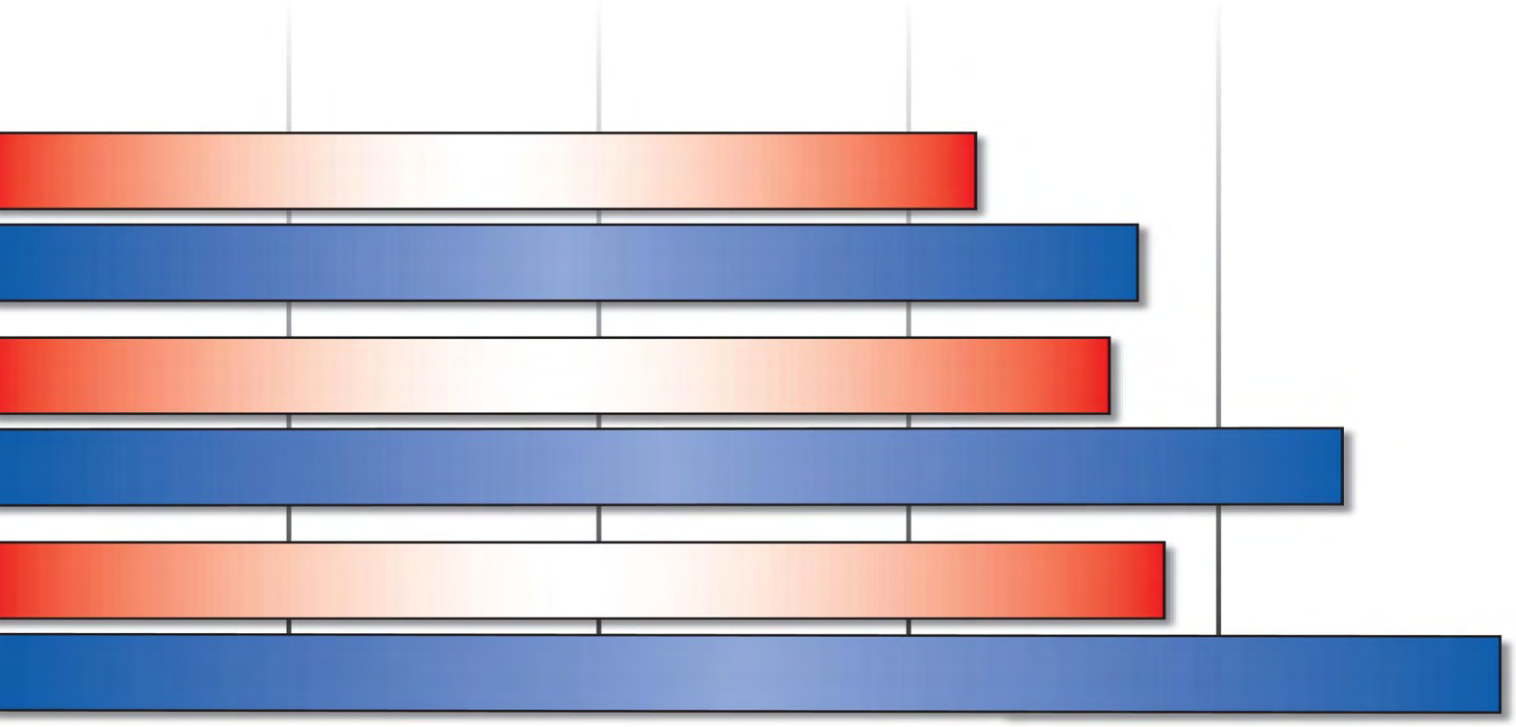
Conclusions

The Stanford CDSMP led to statistically significant, albeit clinically minimal, short-term improvements across a number of health status measures (including some measures of health-related quality of life), healthy behaviours, and self-efficacy compared to usual care. However, there was no evidence to suggest that the CDSMP improved health care utilization. More research is needed to explore longer-term outcomes, the impact of self-management on clinical outcomes, and to better identify responders and non-responders.

Sorting Through the Evidence for the Arthritis Self-Management Program and the Chronic Disease Self-Management Program

Executive Summary of ASMP/CDSMP Meta-Analyses

May 2011



DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Background

Previous meta-analyses of chronic disease self-management programs studied multiple types of self-management programs combined, examined a limited number of outcomes, and were restricted to randomized controlled trials (RCTs). Results of the previous meta-analyses generally showed small to moderate short-term effect sizes (ES).

Purpose

Meta-analyses were conducted to examine the specific effects of two self-management education programs developed at Stanford University. The programs, which were designed to help people with chronic conditions gain confidence in their ability to control their symptoms and the impact of their conditions on their lives, are (1) the Chronic Disease Self-Management Program (CDSMP), a 6-week series of classes, and (2) the Arthritis Self-Management Program (ASMP), a similar series of classes designed specifically for people with arthritis. These investigations included all eligible and available studies of the effects of these two programs (both RCTs and longitudinal program evaluations) and examined multiple outcomes that reflected physical and psychological health status (including self-efficacy), health behaviors, and health care utilization. An additional meta-analysis examined whether the effects of the interventions varied by participant characteristics or implementation factors.

Hypotheses

For each intervention, the hypothesis was that participation in the intervention improved health status, health behavior, and health care utilization outcomes.

A further hypothesis was that the effects of the interventions differed by participant characteristics (age, race or ethnicity, education level) and implementation factors (intervention setting, leader characteristics, recruitment methods, delivery fidelity).

Methods

Search Strategy

A literature search was conducted for the period January 1, 1984–September 30, 2009. Eight electronic databases, including Cochrane, CINAHL, ERIC, EMBASE, Medline, and PsycINFO, were searched to identify relevant studies published in peer-reviewed journals, online publications, and grey literature (such as dissertations, conference abstracts, and unpublished reports). Subject matter experts and stakeholders convened to provide feedback on the project and to identify additional grey literature. The reference lists of all studies located were hand searched to identify other relevant studies. This search strategy identified 297 articles and reports.

Inclusion and Exclusion Criteria: Studies were included if they met all of the following inclusion and exclusion criteria.

- Inclusion Criteria:
  - Intervention was CDSMP or ASMP, regardless of mode of delivery.

- Intervention was implemented in an English-speaking country (United States, United Kingdom, Australia, Canada, New Zealand) regardless of language of implementation.
- Study contained at least one primary outcome measure (defined as energy, fatigue, self-rated health, pain, self-efficacy, health distress, physician visits, or emergency room visits) and outcomes were from an RCT or program evaluation with pre- and posttest measures.
- Study or evaluation report was available in English.

- Exclusion Criteria:
  - Intervention was implemented in combination with another intervention.
  - Intervention did not take place in a native English–speaking country.
  - Instructors did not use program manual provided at leader training.
  - New content (beyond the program manual) was introduced at intervention sessions.

ELIGIBILITY REVIEW AND DATA COLLECTION

A two-person team reviewed each article or report and determined that 61 studies were eligible. Data on the outcomes, participants' characteristics, and implementation factors were abstracted from these studies by the same reviewers. Following abstraction, principal investigators (PIs) were contacted to provide missing data for 55 of the studies (three PIs could not be located). Additional data were received for 51 studies (93% response rate).

DATA ANALYSIS

Unless otherwise noted, ASMP and CDSMP were analyzed separately. Because the majority of eligible studies for both interventions were conducted in an English-speaking small-group setting, the meta-analyses focused on that intervention delivery mode and other intervention delivery modes were analyzed separately. All outcomes were examined at two follow-up times (the time elapsed between baseline and follow-up): short term (4–6 months) and long term (9–12 months). Following the primary analysis, an exploratory analysis was conducted to examine the potential moderating effects of participants' characteristics and implementation factors. That analysis combined all ASMP and CDSMP studies of small-group delivery modes (in English, Spanish, or translated into another language).

Meta-Analytic Procedures: For each meta-analysis of outcomes, pooled ES were generated by combining the results of all eligible studies. For results from longitudinal evaluation studies, the ES was the net difference between baseline and follow-up measures. For RCTs, the ES was the net difference between the intervention and control groups. Pooled ES were derived using a random effects model, which allowed for both within-study and across-study variation of the intervention effects. The sign of the ES was standardized to the direction associated with positive impact. For each outcome, the number of studies analyzed differed depending on the number of studies in which that outcome was reported. All analyses were conducted using Comprehensive Meta-Analysis (Version 2) software. Using the convention established by Cohen for social and behavioral science studies, ES of less than $\pm$ 0.20 were considered small, $\pm$ 0.20–0.80 were considered medium, and greater than $\pm$ 0.80 were considered large.

Evaluation of Heterogeneity: Heterogeneity was tested to determine whether or not there was a statistically significant difference in ES of outcomes across studies. Both the Q-statistic and the I-squared statistic were used; a significant Q-statistic ($p \leq 0.05$) indicated significant heterogeneity (i.e., a statistically significant difference in ES across studies). Heterogeneity was tested for the following:

- To determine whether there was variation in ES by study design (RCT versus longitudinal evaluation). Statistically significant differences in ES by design would suggest that at least some of the change in outcome was attributable to the study design.
- To assess variation in the overall ES for each outcome across studies of the small-group English-speaking mode of delivery.

KEY FINDINGS

ARTHRITIS SELF-MANAGEMENT PROGRAM (ASMP)

Characteristics of Studies

- ***Studies Included:*** A total of 24 studies were included in the analysis of the ASMP.
  - Most (19 of 24) of the ASMP studies used English-speaking small-group delivery mode , so these studies were used for the majority of the analyses.
  - One to two studies used each of the remaining intervention delivery modes (Spanish-speaking small group, French translation of English-speaking small group, Internet, self-tailored self-study, and computer-tailored self-study). Those studies were included in the analysis of heterogeneity by delivery mode.
- ***Demographics***: The 24 ASMP studies included 6,812 participants (1,962 were enrolled in RCTs and 4,850 were enrolled in longitudinal studies).
  - Of the participants, 82% were women.
  - In studies where age was reported, participants were primarily aged 65 years or younger in 21 study arms and aged 65 years or older in 9 study arms.
- ***Publication Bias:*** Funnel plots revealed no evidence of publication bias.

Heterogeneity by Study Design

The analysis of heterogeneity by study design (RCT and longitudinal) was based on data from the short-term follow-up (4–6 months) of English-speaking small-group interventions. Only 2 of 16 variables showed statistically significant heterogeneity, indicating that it was statistically sound to analyze the overall ES for each outcome by combining the effects of RCTs and longitudinal studies.

- Significant Heterogeneity:
  - Pain: Pain reduction was significantly higher in the longitudinal studies (ES = -0.225, $p < 0.001$) than in RCTs (ES = -0.039, $p = 0.495$).

- Physician visits: There was a small significant decrease in physician visits in longitudinal studies (ES = -0.120, $p < 0.001$) but a non-significant (ns) increase in physician visits (ES = 0.141, $p = 0.148$) for RCTs.

RCT-Only Results

In the analysis of the six English-speaking small-group intervention RCTs (4–6 months), significant ES were small to moderate. Self-efficacy (for pain and other symptom management, both ES = 0.340) and communication with physician (ES = 0.277) increased and fatigue (ES = -0.210), anxiety and depression (both ES = -0.200) decreased.

Overall Effects at 4–6 Months and 9–12 Months

- ***Self-Efficacy:*** Whether measured across multiple dimensions or specific to managing pain and other symptoms, and whether measured in RCTs or longitudinal studies, self-efficacy increased moderately (statistically significant) in the short term and persisted longer term (9–12 months).
  - General self-efficacy: ES = 0.240 (4–6 months) and ES = 0.200 (9–12 months)
  - Self-efficacy for pain management: ES = 0 .383 and ES = 0.325
  - Self-efficacy for management of other symptoms: ES = 0.353 and ES =0.336
- ***Psychological Health Status:*** Outcomes (for health distress, depression, and anxiety) showed consistent small to moderate improvements in overall analysis, RCTs, and longitudinal studies. These benefits persisted at 9- to 12-month follow-up.
  - Health distress: ES = -0.359 (4–6 months) and ES = -0.304 (9–12 months)
  - Depression: ES = -0.171 and ES = -0.210
  - Anxiety: ES = -0.200 and ES = -0.224
- ***Physical Health Status:*** Changes (in fatigue, pain, and functional disability) were less consistent than the changes in psychological health status outcomes.
  - Fatigue was reduced significantly in the overall analysis at 4–6 months. The reductions persisted at 9–12 months but ES were small (ES = -0.146 at 4–6 months and ES = -0.214 at 9–12 months).
  - Functional disability was significantly reduced at 4–6 months but the reduction was very modest (ES = -0.049) and did not persist at 9–12 months.
  - There was not a significant reduction in pain in the overall analysis (at 4-6 and 9-12 months), although a moderate change was seen in longitudinal studies at 4–6 months (ES = -0.225).

- ***Health Behaviors:*** Outcomes (exercise, cognitive symptom management, and communication with physician) all showed statistically significant moderate improvements at 4–6 months that persisted at 9–12 months for all but exercise behaviors. Only one RCT measured health behaviors so these results were based primarily on the longitudinal studies.
  - Cognitive symptom management: ES = 0.533(4-6 months) and ES = 0.402 (9-12 months)
  - Communication with physician: ES = 0.255 and ES = 0.313
  - Aerobic exercise: ES = 0.209 and ns
  - Stretching/strengthening exercises: ES = 0.179 and ns
- ***Health Care Utilization:*** Limited data were available on ASMP. Only physician visits were measured. Physician visits did not decrease significantly in the 4- to 6-month overall analysis but there was a small and significant decrease (ES = -0.12) for the longitudinal studies.
- ***Self-Rated Health*** *and* ***Social/Role Limitations:*** Measures did not change significantly.

Effects by Mode of Intervention Delivery at 4–6 Months

- ***Studies included:*** All 24 studies were included in the analysis of effects at 4–6 months by ASMP delivery mode. The analyses included19 small-group English-speaking studies; 2 small-group Spanish-speaking ASMP studies; and 1 study each for French translation, Internet delivered, computer-tailored self-study, and self-tailored self-study. Because of the small number of studies, results of the analysis for the other delivery modes should be considered exploratory only. The number of outcomes evaluated for each intervention mode is indicated in parentheses.
- ***Spanish-Speaking Small Group*** (7 outcomes): Two outcomes showed significant change: a large reduction in pain (ES = -0.740) and an increase in overall self-efficacy (ES = 0.733). The ES for pain and self-efficacy were significantly larger than for any other intervention mode.
- ***Self-Tailored Self-Study Intervention*** (11 outcomes): Significant moderate positive effects were reported for all but four outcomes (self-rated health, health distress, physician visits, and social/role limitations). Of the outcomes measured in this delivery mode, significant positive effects were reported for all the same outcomes as the English-speaking small-group intervention except health distress and physician visits.
- ***Internet Delivered*** (11 outcomes): Two outcomes showed significant positive effects: pain (ES = -0.277) and functional disability (ES = -0.203). The Internet-delivered intervention was not effective for any of the same outcomes as the English-speaking small-group intervention with the exceptions of pain and functional disability.
- ***Computer-Tailored Self-Study*** (4 outcomes): Overall self-efficacy (ES = 0.393) and functional disability (ES = -0.204) showed significant and moderate positive effects. The effects for pain and physician visits were not significant.

- ***French Translation Delivered in Small Group*** (8 outcomes): The intervention was not effective for any of the same outcomes as the English-speaking small-group delivery mode except for stretching/strengthening exercises (moderate and statistically significant positive effect [ES = 0.340]).

CHRONIC DISEASE SELF-MANAGEMENT PROGRAM (CDSMP)

Characteristics of Studies

- ***Studies included***: A total of 23 studies were included in the analysis of the CDSMP.
  - 18 of the 23 used the English-speaking small-group mode of delivery.
  - The studies included two each for Spanish-speaking small-group and Internet-delivered interventions and one for the each of the remaining delivery modes (translations of English small group and home-based peer led).
- ***Demographics:*** The 23 studies included 8,688 participants (2,902 were enrolled in RCTs and 5,779 in longitudinal studies).
- ***Publication Bias:*** Funnel plots revealed no evidence of publication bias.

Heterogeneity by Study Design

There was no heterogeneity in effects by study design for any of the 16 outcomes at short-term follow-up (4–6 months) for the English-speaking small-group interventions. Therefore, it was statistically valid to analyze overall ES for RCTs and longitudinal studies combined.

RCT-Only Results

In the short-term follow-up of the English-speaking small-group studies, the analysis of the five RCTs demonstrated significant small to moderate ES for self-efficacy (ES = 0.427), health distress (ES = -0.215), social/role limitations (ES = -0.209), aerobic exercise (ES = 0.197), cognitive symptom management (ES = 0.312), and days or nights hospitalized (ES = -0.138).

Overall Effects at 4–6 Months and 9–12 Months

- ***Self-Efficacy:*** When measured across multiple dimensions or specific to managing pain and other symptoms, and whether examined overall or by study design, self-efficacy showed moderate and significant increases in the 4- to 6-month and 9- to 12-month analyses.
  - General self-efficacy: ES = 0.345 (4-6 months) and ES = 0.204 (9-12 months)
  - Self-efficacy for disease management: ES = 0.260 and ES = 0.377
  - Self-efficacy for management of other symptoms: ES = 0.283 and ES = 0.450
- ***Psychological Health Status:*** Outcomes (for health distress and depression) showed consistent small to moderate improvements in both the 4- to 6-month and 9- to 12-month follow-up in both overall effects and by study design.
  - Health distress: ES = -0.282 (4-6 months) and ES = -0.227 (9-12 months)

- Depression: ES = -0.216 and ES = -0.210

- ***Physical Health Status:*** Changes (in energy, fatigue, pain, functional disability, and shortness of breath) were less consistent than changes in the psychological health status variables.
  - Energy and fatigue showed small but significant improvements at 4–6 months (ES = 0.158 and ES = -0.138, respectively) but they did not persist at 9–12 months.
  - There were non-significant changes in pain and shortness of breath at 4–6 months but small and significant changes at 9–12 months (ES = -0.126 and ES = 0.102, respectively). In the 4- to 6-month analyses, both outcomes had small but statistically significant changes in the longitudinal studies but not in the RCTs and hence the changes are of questionable importance.
  - Functional disability showed no significant changes in overall effects in the analyses at 4–6 months and 9–12 months.

- ***Health Behaviors***: Of the four behaviors evaluated (aerobic exercise, cognitive symptom management, communication with physician, and stretching/strengthening exercise), three showed small to moderate significant improvements in the overall analysis at 4–6 months. Most improvements persisted at 9–12 months.
  - Cognitive symptom management: ES = 0.261 (4-6 months) and ES = 0.374 (9-12 months)
  - Aerobic exercise: ES = 0.118 and ES = 0.098
  - Communication with physician: ES = 0.256 and ns
  - Stretching/strengthening exercise: ES = ns and ES = 0.153

- ***Health Care Utilization:*** Changes were minimal. Three of the four variables measured showed no significant effect sizes at 4–6 months or 9–12 months. There was a small but significant change in the fourth measure, days in the hospital, at 4–6 months (ES = -0.088) that did not persist at 9–12 months. Of note, the small but significant effect was seen in both RCTs and longitudinal studies at 4–6 months.

- ***Self-Rated Health:*** Measures improved modestly but significantly at 4–6 months (ES = 0.143) but did not persist at 9–12 months.

- ***Social/Role Limitations:*** Measures showed a small but significant effect at 4–6 months that persisted at 9–12 months (ES = -0.167 and ES = -0.141, respectively). These significant effects were found in both RCTs and longitudinal studies at 4–6 months.

Effects by Mode of Intervention Delivery at 4–6 Months

- ***Studies Included:*** Analysis included 15 English-speaking small-group studies and 2 Spanish-speaking small-group studies; 1 study conducted in Europe in four different languages; 2 studies of Internet-delivered interventions; and 1 home-based peer-led intervention study (one arm delivered over the telephone and one arm delivered in person at home). Similar to the ASMP analysis by mode of intervention delivery, because of the small number of studies,

results of the analysis for other delivery modes should be considered exploratory only. The number of outcomes evaluated for each intervention mode is indicated in parentheses.

- ***Spanish-Speaking Small Group*** (12 outcomes): For the Spanish-speaking small-group intervention, six outcomes showed statistically significant benefits: self-rated health (ES = 0.308), pain (ES = -0.279), self-efficacy (ES = 0.372), health distress (ES = -0.549), social/role limitations (ES =-0.301), and aerobic exercise (ES = 0.329).

- ***English Small-Group Translation*** (12 outcomes): Four outcomes showed statistically significant improvements: energy (ES = 0.385), fatigue (ES = -0.237), self-rated health (ES = 0.385), and cognitive symptom management (ES = 0.385).

- ***Internet Delivered*** (15 outcomes): Only three outcomes were significant: fatigue (ES = -0.143), pain (ES = 0.141), and health distress. (ES = -0.261)

- ***Home-Delivered Peer Led*** (3 outcomes): None of the outcomes in the home-based peer-led intervention showed statistically significant benefits.

- For one outcome, the ES between modes of delivery were significantly different. For pain, the Spanish-speaking small-group intervention showed a moderate reduction (ES = -0.279), whereas the English-speaking small-group and the Internet modes of delivery showed only small reductions (ES = -0.160 and ES = -0.114, respectively). For all other outcomes, there were no significant differences in the ES across modes of delivery.

ANALYSIS OF PARTICIPANT AND IMPLEMENTATION FACTORS

Studies Included

All ASMP and CDSMP small-group interventions, regardless of language of delivery, that reported 4- to 6-month outcomes were combined for the moderator analysis which examined whether the intervention effects varied by participant characteristics and implementation factors. This analysis comprised 34 studies with 44 study arms. Results from this moderator analysis should be interpreted as exploratory because of limited reporting of participant characteristics and implementation factors and lack of differentiation among the categories in some of the variables of interest.

Socio-demographics

- ***Number of Participants Studied:*** 10,792 participants were studied (5,111 in RCTs and 5,681 in longitudinal evaluations).

- ***Age:*** In the 64% of the study arms reporting age, participants were predominantly aged 65 years or younger.

- ***Education:*** In the two-thirds of studies reporting education level, the majority of participants had more than 12 years of education.

- ***Race or Ethnicity:*** Both interventions were conducted in primarily white populations, although three study arms focused on primarily black populations and four were conducted in primarily Hispanic populations.

Self-management Interventions for Pain and Physical Symptoms Among People Living With HIV: A Systematic Review of the Evidence

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Introduction: Pain and symptoms still persist among people living with HIV/AIDS. Evidence-based self-management interventions have the potential to help people with HIV/AIDS to successfully manage pain and symptoms. We aimed to identify and appraise the evidence regarding the effectiveness of self-management interventions for pain and/or physical symptoms in people living with HIV/AIDS.

Methods: We searched for controlled intervention studies in Amed, Assian, CINAHL, Cochrane Library, Embase, Medline, PsycInfo, Scopus, and Web of Science data bases, from 1984 to February 2017. Two reviewers screened and extracted data, assessed risk of bias (using Joanna Briggs Institute Critical Appraisal checklist for randomized and nonrandomized trials), and rated the quality of evidence (GRADE tool).

Results: We identified 22 original papers reporting 19 different studies. Of these, 17 used randomized controlled trial designs. Three studies reported data on pain severity, and 2 studies reported data on pain interference outcomes with one study reporting positive effect on both outcomes. Outcomes for physical symptoms were reported in 13 studies with 6 studies reporting positive effect. The quality of evidence was moderate for pain outcomes. For physical symptoms, one study was rated as moderate; the rest were rated as low n = 8 and very low n = 4 quality.

Conclusions: There is some evidence to suggest that self-management interventions delivered either online, face-to-face, or group-based consisting of booklet, leaflet, or manuals are effective in improving pain and physical symptoms. Findings suggest the need for theoretically plausible high-quality clinical trials of pain and physical symptom self-management among culturally diverse people with HIV.

Key Words: pain, physical symptoms, self-management interventions, randomized/nonrandomized controlled trials, HIV/AIDS

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INTRODUCTION

Evidence shows a substantial decline in mortality among people living with HIV (PLWH) resulting in increased life expectancy.[1,2] PLWH experience a high burden of pain and physical symptoms. It is hypothesized that PLWH experience pain because of severity of their underlying HIV infection and side effects of HIV treatment.[3] Recent evidence also suggests inflammation as a potential etiology.[4] A systematic review of pain in HIV/AIDS reported that pain prevalence ranges from 54% (point prevalence) to 83% (3-month period prevalence).[5] Peripheral neuropathy (PN) is common in HIV infection despite the use of effective antiretroviral therapy (ART),[6] with a prevalence range of 44%–60%.[7–9] Longitudinal studies conducted in high-income countries report that the prevalence of PN is increasing, despite the decline in use of neurotoxic drugs.[10,11] An observational cohort study reported a prevalence of mild PN of 38%. It is often under recognized and, given the increased survival of PLWH, the prevalence of this problem is actually greater than the historically reported rates of severe PN from studies conducted before ART.[12] Pain is considered chronic if it has a duration of at least 3 months beyond the period of normal healing.[13] Pain in HIV is often undertreated, underreported, and unlikely to be routinely assessed.[14]

PLWH also experience a high burden of physical symptoms[15,16] from diagnosis,[17,18] in advanced disease and

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Self-Management Education Programs for People Living with HIV/AIDS: A Systematic Review

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Abstract

The effectiveness of self-management programs to improve physical, psychosocial, health knowledge, and behavioral outcomes for adults living with HIV has not been well established. This article reviews the effectiveness of self-management education programs to improve physical, psychosocial, health knowledge, and behavior outcomes for adults living with HIV/AIDS. A systematic review of English articles using CINAHL, MEDLINE, and PsycINFO were used to identify and retrieve relevant studies. Each database was searched from its earliest record to October 2010. Search terms included HIV/AIDS, self-management, self-care, patient education, and education programs. Only studies that (1) reported on a HIV-specific intervention that aimed to increase participants HIV-related knowledge through a self-management component, (2) included a control group, (3) provided skills training or targeted behavior change, and (4) reported clinical outcomes were included. Independent data extraction by one author using the methods described in the Cochrane Handbook for Systematic Reviews. A second reviewer checked the data extraction. Six protocols were reported in eight publications ($n = 1178$), all contained elements of self-management interventions. Effect size calculations were not conducted due to limitations in the available data. The review found randomized controlled trials (RCT) evidence sufficient to infer that self-management programs for people living with HIV/AIDS result in short-term improvements in physical, psychosocial, and health knowledge and behavioral outcomes. Statistically significant improvements were reported for intervention participants compared to control participants across most outcomes. There is insufficient evidence to provide conclusions regarding the long-term outcomes of HIV-specific self-management interventions.

Introduction

Medical advances in the treatment of HIV/AIDS have reduced disease progression and significantly extended life expectancy.[1,2] Consequently, the estimated 3.7 million people living with HIV across Australia, Europe, and America today experience a chronic condition requiring ongoing management.[3] While the incidence of new HIV diagnoses worldwide continues to decline, increased survival rates associated with highly active antiretroviral treatment (HAART) means that the number of people living with HIV is rising and this population is aging. The financial burden of HIV is considerable with an American study estimating the cost of lifetime HIV health care to be $618 900 (U.S.) for a life expectancy of 24.2 years postinfection.[4]

The transition of HIV from an acute to a chronic condition means that people living with HIV are now required to take more responsibility for the management of their condition, including making physical, psychological, and social adjustments. Self-management of chronic conditions targets reducing disease progression, managing symptoms and the prevention of disability.[7] Adherence to complex medication regimens often forms a substantial aspect of managing a chronic condition. People living with HIV are required to undertake medication regimens that demand a high degree of adherence and attend 3 to 6 monthly medical appointments. Additionally, they may experience unpleasant side effects resulting from their HIV medications or the virus itself. Research indicates that while optimal adherence rates are 95% or greater, many people report regularly forgetting to take their

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