AVALON HEALTHCARE SOLUTIONS

THE FUTURE OF TEST SPECIFICITY WITH PRECISION GENETIC TEST MANAGEMENT

January 24, 2023

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OVERVIEW & INTRODUCTIONS

Barry Davis, Chief Growth Officer, Avalon

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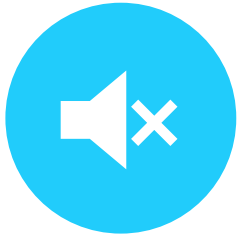
Before We Start

This meeting is being recorded.



We will be **MUTING** everyone except the presenter to make sure the audio is clean and clear.

Q&A will be done by using the **“Questions” feature**.

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Agenda

OVERVIEW & INTRODUCTIONS
Barry Davis, Chief Growth Officer, Avalon

MOLECULAR TESTING CONTROLS
Gabriel Bien-Willner, M.D., Medical Director, MolDX, Chief Medical Officer, Palmetto GBA

POLICY AND Z-CODES FOR COMMERCIAL POPULATIONS
Rahul Singal, M.D., Chief Medical Officer, Avalon

PRECISION GENETIC TEST MANAGEMENT
Sarah Bretz, Product Manager, Avalon

WHAT'S THE LATEST FROM WASHINGTON, D.C.?
Julie Barnes, Principal, Maverick Health Policy

CLOSING REMARKS
Barry Davis, Chief Growth Officer, Avalon

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MOLECULAR TESTING CONTROLS

Gabriel Bien-Willner, M.D., Medical Director, MolDX;
Chief Medical Officer, Palmetto GBA

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MolDX Program History

- Current automated controls and procedures for molecular diagnostic tests developed over the last decade and originated with unmet needs in Medicare.
- The MolDX program was created in 2011 to try to understand the molecular diagnostic testing landscape, create policies, and more importantly, create controls governed by a foundational policy: LCD35025 that required labs to:
  - Register their test with the DEX registry and get a unique identifier (Z-Identifier code). This allows the payor to appropriately adjudicate claims for that SPECIFIC test.
  - Go through a technical assessment (TA) of the specific service to ensure the service meets governing policy requirements by demonstrating analytical validity, clinical validity, and clinical utility (AV, CV, and CU).
- The program has evolved substantially over the last 12 years to be scalable, fair, and equitable to providers and payors alike. The procedures and controls created in a very difficult environment has resulted in automated solutions that have demonstrated transparency and assurance to providers, increased access to care to beneficiaries, and decreased costs to payors.

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Why molecular tests are different and require special attention

- **MolDX was created because molecular tests were and are still rapidly evolving, and have unique attributes not shared with other medical or even laboratory services:**
  - **Understanding molecular tests require knowledge and experience most clinicians (and policy writers) may lack**
  - **Lack of well-defined billing codes makes claims processing difficult; many are not sufficient to understand what was done**
  - **Lack of standardization in testing makes it difficult to know if any given test is both reasonable and necessary**

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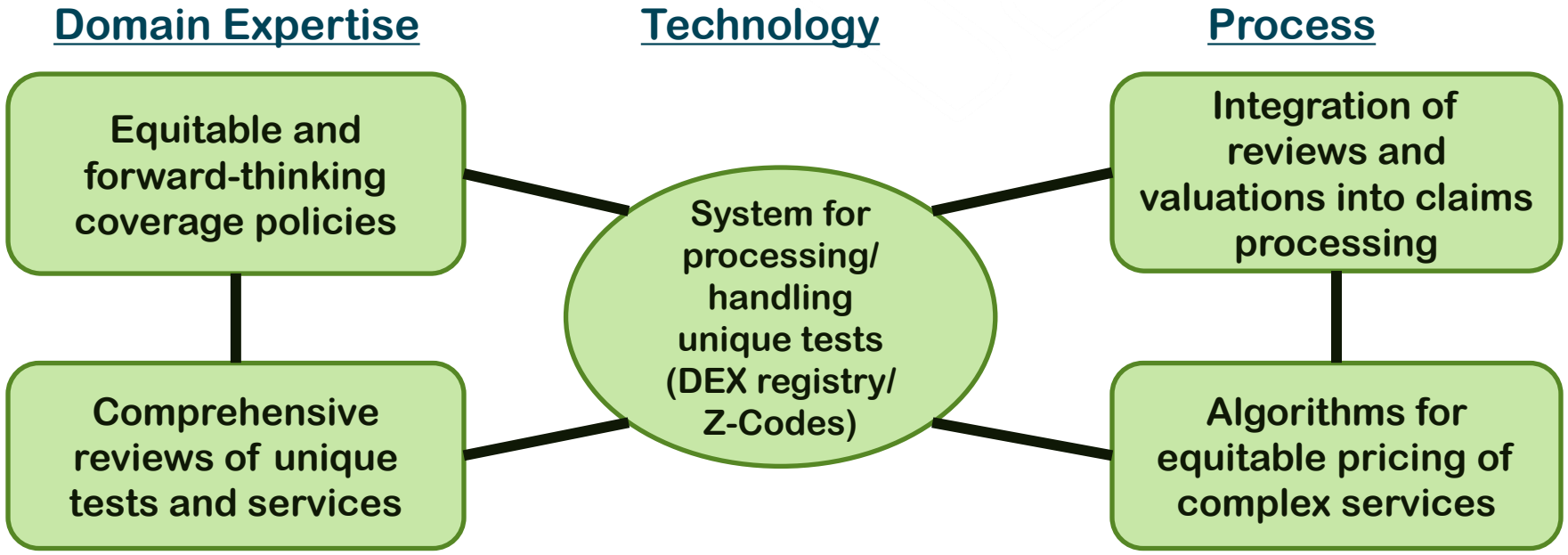
Palmetto GBA solutions for molecular testing

- 12 years of development in this space has yielded complete solutions to complex problems



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Different approaches to adjudication

- **Palmetto GBA has created processes, procedures, and controls that result in the automation of adjudication of molecular claims by determining *a priori*:**
  - **If the *specific* test is the appropriate test for the patient**
  - **If the *specific* test does what it says it does**
  - **If the *specific* test is of sufficient quality**
  - **If the *specific* test has demonstrated clinical value**
  - **If the *specific* test is billed appropriately**
- **These PAYOR CONTROLS were created for the MolDX program for CMS but are applicable to all payors**
- **Z-Codes and registration allow automated determination for specific test**
- **Technical Assessments (TAs) allow evaluation of each test for medical necessity and quality**

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Lab Process for Z-Code and CMS FFS Coverage Decision

Standard payor process (single claim approach)

*pre-authorization

Lab performs service → Lab bills service → Payor reviews claim, determines if covered → Single Claim adjudicated

Questions asked:
- What is this test?
- Is this the right test for this patient?
- is this test necessary?

Performed for each claim

Palmetto GBA process (test evaluation) BEFORE claims submitted

Performed ONCE for class/type of service

Service selected for review (non-established test) → Evidentiary review (literature, practice norms) → formulate established test process for evaluation → Create TA SOP, automated edit logic, forms for labs → New Established test in production

Step 1: Create established test

Lab registers service for Z-Code → Z-Code generated → Lab submits additional data (if needed) → TA performed (according to SOP for established test) → Automated adjudication based on result of TA

Step 2: Technical assessment

Performed ONCE for each test submission, claims processing is automated

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The TA process review: What we look for:

TA includes assessment of a tests':

1. **Analytical validity (AV)**
   AV: How well does the test detect the mutation/compound it is seeking to detect? *Analytical and Clinical validations*
2. **Clinical Validity (CV)**
   CV: How well does the analyte/variant relate to the presence/risk of disease?
3. **Clinical Utility (CU)**
   CU: How clinically useful is this test? Can it change management to improve patient outcomes?

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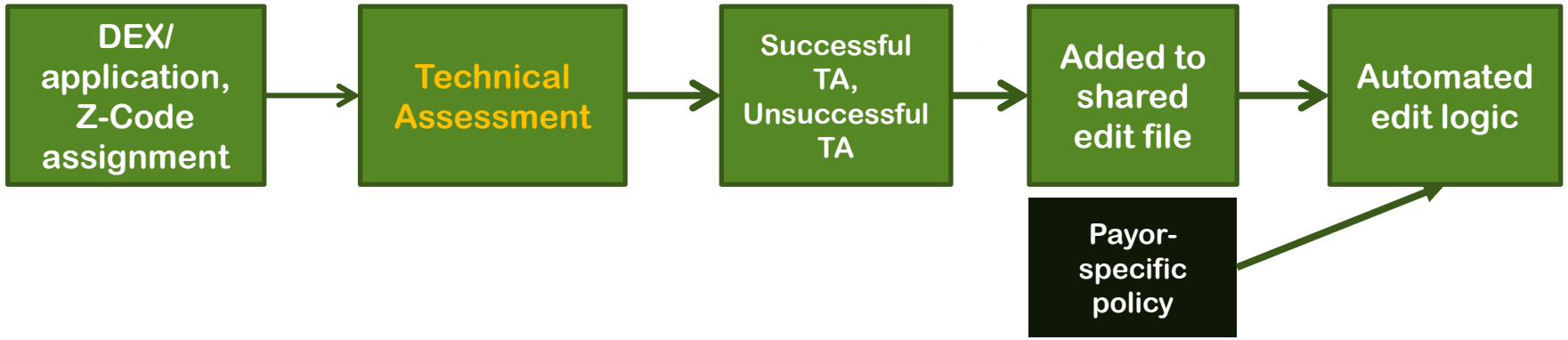
TA Workflow to Automation

1. Tests covered under existing LCDs, established tests, or established standards of care



Timing: 2 weeks~2 months from receipt of completed documents, depending on test complexity

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Current and future use of the Program

- We began developing the program for CMS in 2011 and have substantially refined and improved the process
- Currently employ 5 full-time SMEs in the field to generate policies and procedures, plus a battery of experts as support staff
- We have assessed over 20,000 tests in our registry, and have more than 50 policies and articles on molecular diagnostic testing
- Expanded beyond Medicare; began roll-out to Medicare Advantage programs in late 2021; recently completed this work
- Currently developing expansion to commercial (non-Medicare) programs; will be available this year:
  - Registrations will begin for all molecular tests to enable correct coding controls
  - Technical Assessments (TAs) will begin with prenatal, hereditary cancer testing (including BRCA) and carrier screening

POLICY AND Z-CODES FOR COMMERCIAL POPULATIONS

Rahul Singal, M.D., Chief Medical Officer, Avalon

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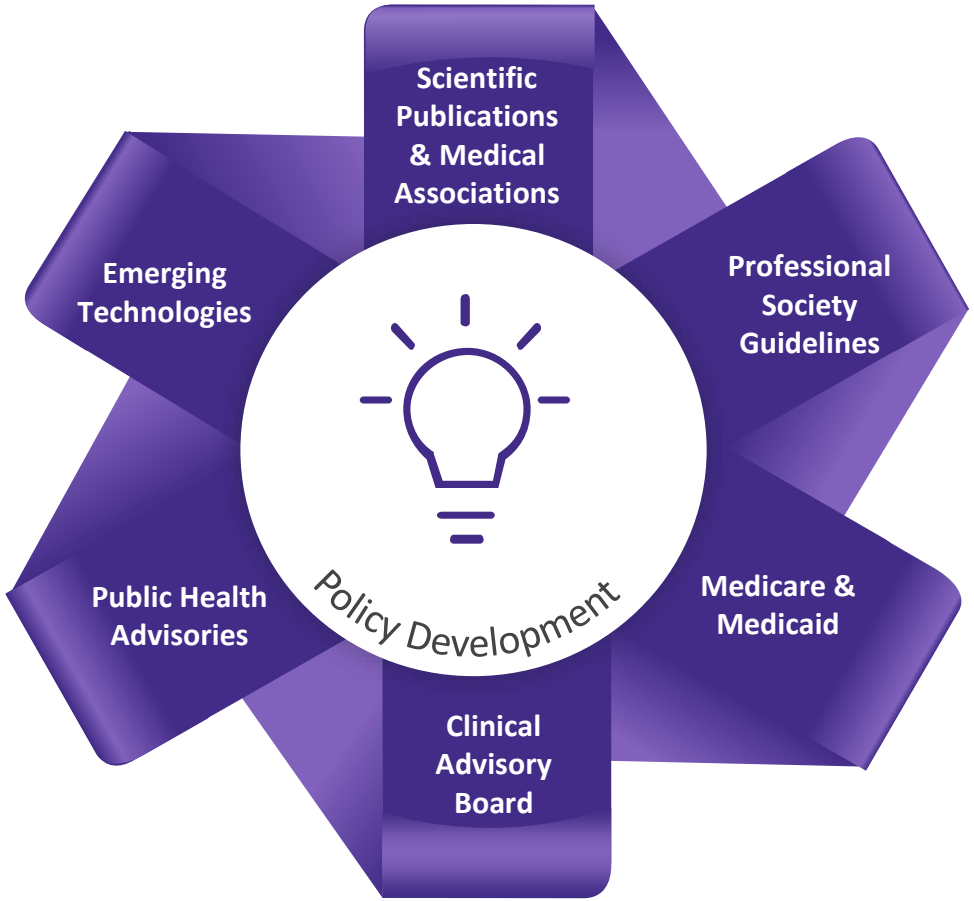
Policy Development: Multiple Sources



Avalon's **dedicated full-time scientists** support and maintain ~65 Routine and ~75 Genetic outpatient laboratory policies

All policies are researched, written, and maintained in-house by **dedicated science team, including PhDs**

Demonstrated conditions of coverage

Each policy has **robust scientific rigor**, typically **using ~ 50 references**

Annual updates reviewed and **approved by** Avalon's independent **Clinical Advisory Board**

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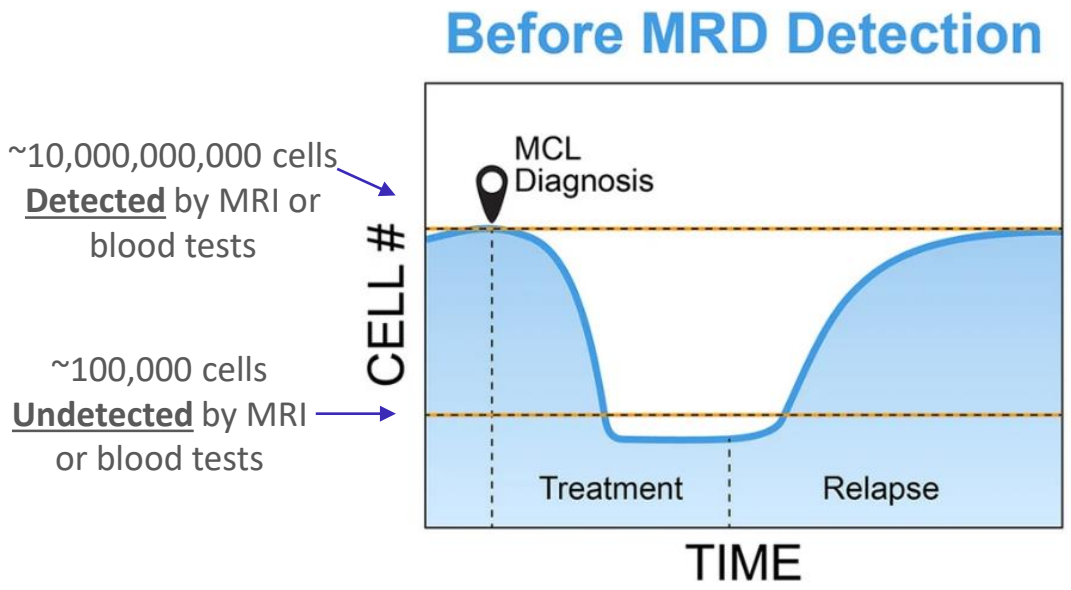
Life Before Minimal Residual Disease (MRD) Testing



- If managing solid tumors or lymphomas, imaging with PET or MRI was optimal modality.
- If managing leukemia, then bone marrow biopsy or peripheral blood screening.
- Follow up chemotherapy could only then be initiated.
- “Maybe in the future, we’ll be able to catch a cancer recurrence earlier” and have better outcomes.
- If chemotherapy was 99.9999% then 1 out of a million cancer cells would survive. If 10B cancer cells, you still have 10,000 cancer cells floating around. If only 100,000 cancer cells, then 90% of the time, you will have a “cure”.
- “This math exercise represents the promise of MRD and which our children may experience” – Rahul Singal, M.D.

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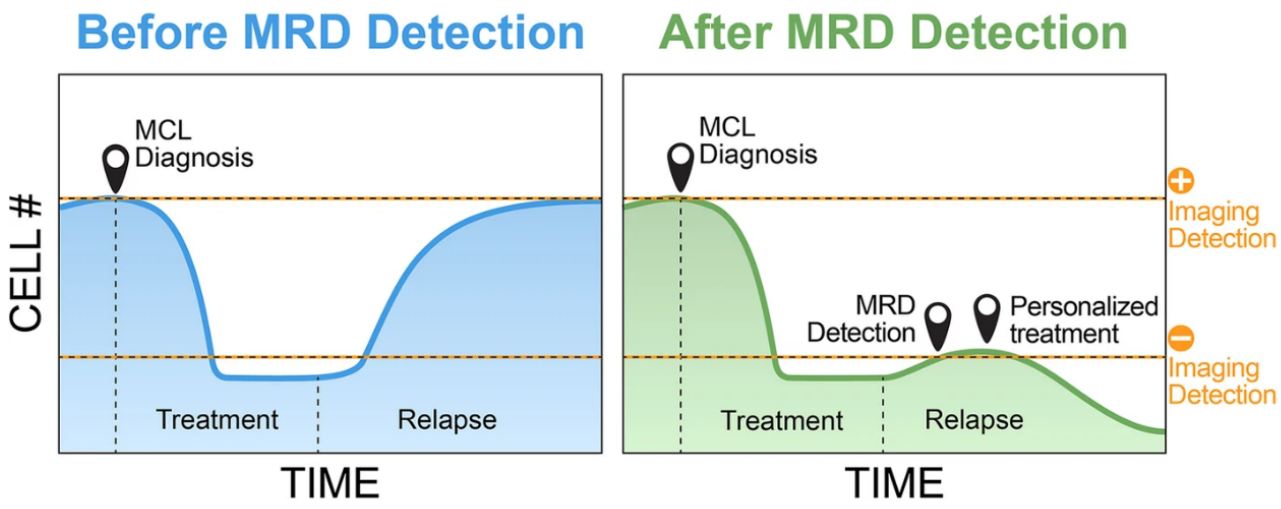
Minimal (or Measurable) Residual Disease (MRD)



General overview of minimal residual disease detection. The figure shows two scenarios emphasizing the importance of MRD detection after initial treatment of mantle cell lymphoma. When MRD detection is not performed, there is no indication of how effective the treatment was on the tumor, and relapse may eventually occur (left). If MRD diagnosis confirms a positive result, the patient can be prescribed to a more personalized treatment to prevent any future relapses (right)

Advances in the assessment of minimal residual disease in mantle cell lymphoma

Dayoung Jung, Preetesh Jain, Yixin Yao & Michael Wang

Journal of Hematology & Oncology **13**, Article number: 127 (2020) | Cite this article

- MRD tests for evidence of cancer recurrence using genetic techniques generally from simple blood tests.
- MRD testing for liquid tumors (e.g., leukemia, lymphoma) have been shown to improve outcomes.
- MRD testing is standard of care (NCCN) after a patient undergoes chemotherapy for these liquid tumors
  - To measure response to chemotherapy cycles. Need to understand profile of remaining cancer cells after each cycle of therapy.
  - MRD testing is also performed after initial remission and on an annual basis to confirm remission.

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Avalon MRD Policy Overview

MULTIPLE METHODOLOGIES CORRESPOND TO MULTIPLE CPTS

Avalon Coverage Criteria

- For individuals with multiple myeloma (MM), chronic lymphocytic leukemia (CLL), or small lymphocytic lymphoma (SLL), minimal residual disease (MRD) testing by multiparameter flow cytometry **or** next-generation sequencing (NGS) **MEETS COVERAGE CRITERIA.**
- For individuals with acute myeloid leukemia (AML) or acute lymphoblastic leukemia (ALL), MRD testing by multiparameter flow cytometry, PCR-based techniques, **or** NGS **MEETS COVERAGE CRITERIA.**
- 81479 – miscellaneous genetic test requires PA.
- Avalon enforcement of flow cytometry is automated .
- 0717U requires PA and remaining are not yet covered.

CPT	Code Description
81479	Unlisted molecular pathology procedure
88184	Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker
88185	Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; each additional marker (List separately in addition to code for first marker)
0171U	Targeted genomic sequence analysis panel, acute myeloid leukemia, myelodysplastic syndrome, and myeloproliferative neoplasms, DNA analysis, 23 genes, interrogation for sequence variants, rearrangements and minimal residual disease, reported as presence/absence Proprietary test: MyMRD® NGS Panel Lab/Manufacturer: Laboratory for Personalized Molecular Medicine
0306U	Oncology (minimal residual disease [MRD]), next-generation targeted sequencing analysis, cell-free DNA, initial (baseline) assessment to determine a patient-specific panel for future comparisons to evaluate for MRD Proprietary test: Invitae PCM Tissue Profiling and MRD Baseline Assay Lab/Manufacturer: Invitae Corporation
0307U	Oncology (minimal residual disease [MRD]), next-generation targeted sequencing analysis of a patient-specific panel, cell-free DNA, subsequent assessment with comparison to previously analyzed patient specimens to evaluate for MRD Proprietary test: Invitae PCM MRD Monitoring Lab/Manufacturer: Invitae Corporation
0340U	Oncology (pan-cancer), analysis of minimal residual disease (MRD) from plasma, with assays personalized to each patient based on prior next-generation sequencing of the

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	patient's tumor and germline DNA, reported as absence or presence of MRD, with disease-burden correlation, if appropriate Protietary test: Signatera™ Lab/Manufacturer: Natera, Inc

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MRD Z-Codes – Select examples

Company	Z-Code	Conditions	Methodology	CPT Code
A	ZB479	ALL, CLL, NHL, MM	PCR (NGS)	81479
A	ZB4E8	CLL, NHL, MM	PCR (NGS)	81479
A	ZB4E9	AML, NHL	PCR (NGS)	81479
A	ZB8D3	ALL, MM	PCR (NGS)	81479
B	Z00D5	cancer/ solid tumors	Hybrid Capture	81479
B	Z00D6	cancer/ solid tumors	Hybrid Capture	81479
C (Univ)	ZB27N	AML	PCR + elecrophr	81479

- Select companies that have been blinded
- Actual table has > 50 columns including genes analyzed, details on methodologies
- For MRD, Avalon for:
  - Company “A” - the 4 specific tests are covered
  - Company “B” – these tests are not covered. Other tests from Company “B” for other indications are covered.
  - Company “C” – has yet to apply to Avalon. Would likely be covered

MRD is a relatively new genetic test for managing cancer patients.

BRCA is still the most common genetic test that Avalon does Prior Auth. BRCA now has over 20 genetic lab providers with over 200 corresponding tests.

Summary Point: What are the best labs and corresponding tests for each condition?

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PRECISION GENETIC TEST MANAGEMENT

Sarah Bretz, Product Manager, Avalon

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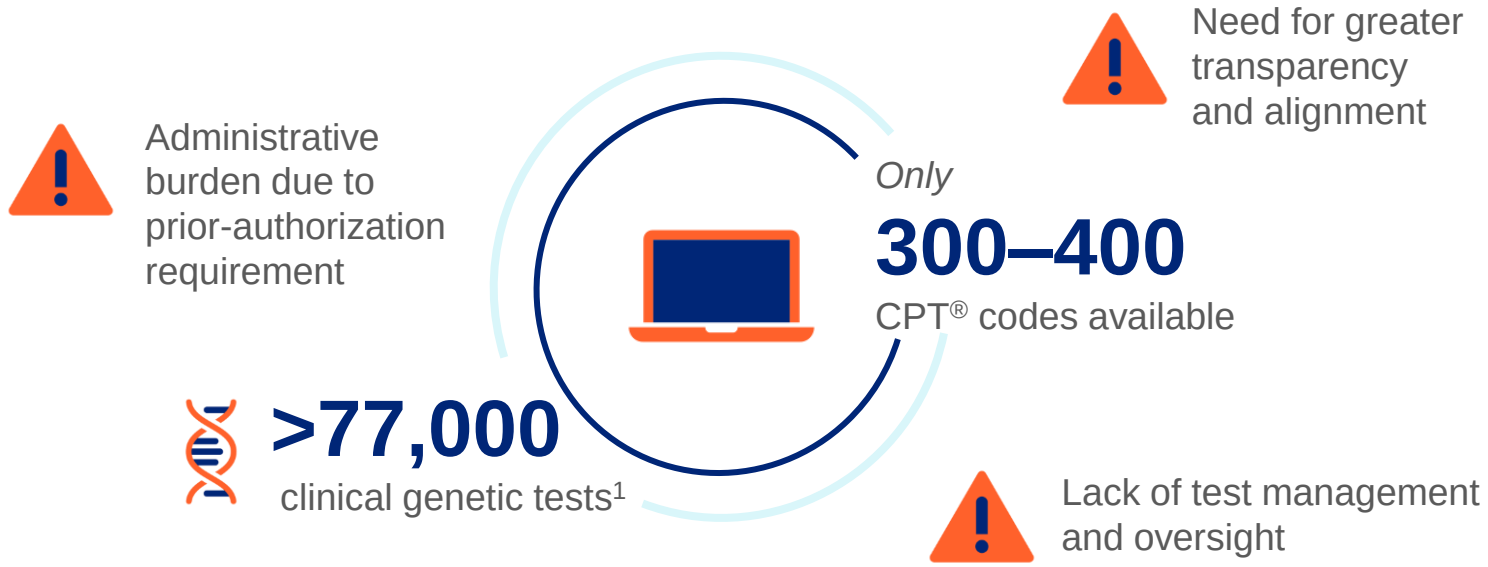
Genetic testing challenges

>40k
different tests associated with CPT 81479

$2B fraud
identified by US DOJ; genetic fraud in non-DEX Z-Code states

Labs **bundle unnecessary tests** into panels
Claims submitted do not match auth approved



1. MedlinePlus [Internet]. Bethesda (MD): National Library of Medicine (US); [updated 2021 Jul 28]. What is genetic testing?; Available from: https://medlineplus.gov/genetics/understanding/testing/genetictesting/#:~:text=More%20than%2077%2C000%20genetic%20tests,risk%20of%20a%20genetic%20disorder.

Legacy solutions are no longer sufficient

Non-integrated solutions are not equipped to solve genetic lab challenges

Policy enforcement with traditional prior authorization

- Abrasive to providers
- CPT codes lack specificity needed to enforce coverage policy rules
- Does not address FWA or panel stuffing
- Does not support MA plan adherence to MoIDX®
- Causes confusion when members receive denial letters

Test quality

- Falls to the health plan; no FDA review of lab developed tests (LDT)
- Quality enforcement through coverage is challenging without a process to perform test specific quality reviews
- May impact members leading to inappropriate therapies and quality of life

Network configuration and reimbursement

- Health plans contract with labs for their entire test portfolio
- Lack of subject matter expertise in health plan to perform quality reviews
- Pay lab tests based on CPT (more than 40k different tests are associated with 81479)

DEX Z-Codes and Fraud Prevention

>$1.2B in alleged fraud

More than $1.2 BILLION

Alleged fraudulent telemedicine, cardiovascular and cancer genetic testing, and DME schemes

13 U.S. FEDERAL DISTRICTS

Fraudulent genetic claims isolated to non-MolDX states that do not require Z-Codes

36 DEFENDANTS

DME and telemedicine providers charged

THE UNITED STATES DEPARTMENT of JUSTICE

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Wednesday, July 20, 2022

Justice Department Charges Dozens for $1.2 Billion in Health Care Fraud

Nationwide Coordinated Law Enforcement Action to Combat Telemedicine, Clinical Laboratory, and Durable Medical Equipment Fraud

The Department of Justice today announced criminal charges against 36 defendants in 13 federal districts across the United States for more than $1.2 billion in alleged fraudulent telemedicine, cardiovascular and cancer genetic testing, and durable medical equipment (DME) schemes.

FRAUD

*Department of Justice, Office of Public Affairs (2022). Justice Department Charges dozens for $1.2 Billion in Health Care Fraud. Retrieved from https://www.justice.gov/opa/pr/justice-department-charges-dozens-12-billion-health-care-fraud.

Precision Genetic Testing Management

What is it?

- **An exclusive extension** of the Medicare FFS MolDX® Program through Palmetto GBA
- **Leverage emerging industry standard DEX™** Diagnostics Exchange test identification codes (DEX Z-Codes) to uniquely identify discrete test quality and ensure consistent coding
- **A focus on test quality** (AV,CV, and CU) and metrics applicable to coverage and point of care decisions
- **Automated** policy enforcement through NCQA-certified prior authorization program
- Scientific, expert-led **Clinical Advisory Board**

Precision Genetic Testing Management

What is the value to you?

Compliance with state Medicaid and MA coverage rules

Improve provider NPS

Increase in auto-approvals for commercial and caid plans and removal of prior auth for MA

Improve quality of care

by ensuring tests meet quality standards

FWA prevention

Z-Code availability on claims

Required for genetic testing payment in

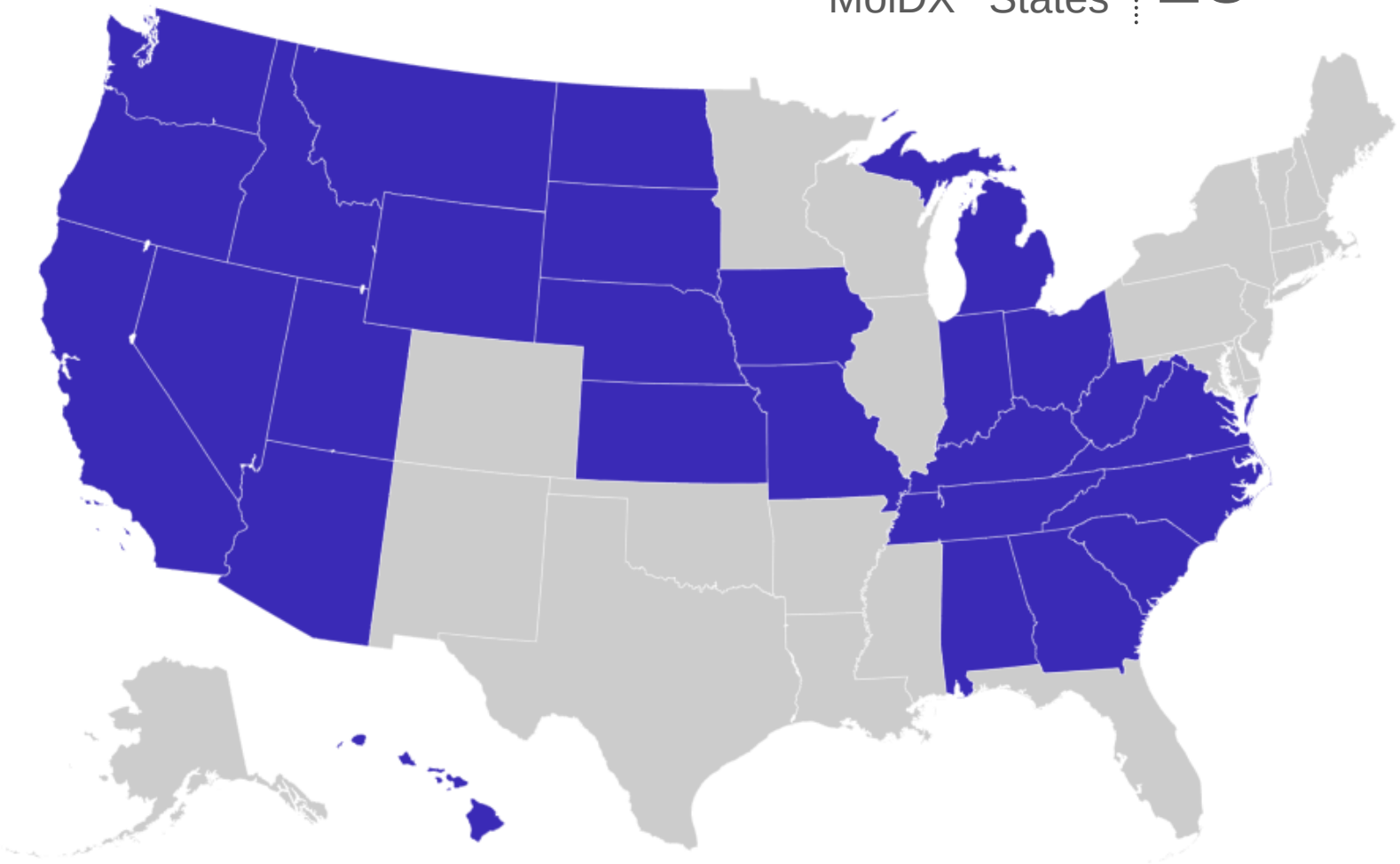
28 states

for Medicare FFS

Emerging as the test registration and coverage standard

18K+ vetted genetic tests

Participating MolDX® States 28



Z-Codes on claims

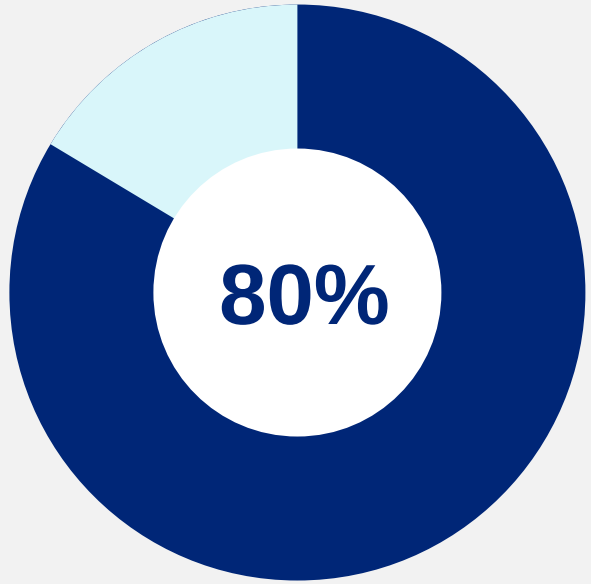
Background

Analyzed one-year of commercial claims data to understand how many providers, submitting claims to the health plan, had a test with a DEX Z-Code

Finding

- Approximately 55,000 unique genetic tests billed in one year
- Approximately 8% of unique tests were billed greater than five times
- Approximately 173 tests accounted for 63% of spend

Tests by greatest spend that included a DEX Z-Code



Percentages are estimates only based on research and analysis completed August 2022 by Optum LBM team

Prior Authorization enforcement using Z-Codes

- No prior auth for genetic testing

- Z-Codes are requested as part of the prior auth process

- Automated approvals
- Claims are matched to authorizations

Genetic testing management innovation

DEX Z-Codes are the standard for driving efficiency, test quality, and saving in your genetic management solution

BETTER **QUALITY**

Investing in industry standards to enforce test quality

DRIVE **SAVINGS**

Achieve affordability and increase market competitiveness

COMPLIANCE WITH DEFENSIBLE CONTENT

With MoIDX, state Medicaid and MA coverage rules

IMPROVED **PROVIDER EXPERIENCE**

Cultivating stronger relationships with labs and members

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WHAT'S THE LATEST FROM WASHINGTON, D.C.?

Julie Barnes, Principal, Maverick Health Policy

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"It's not how you start; it's how you finish."

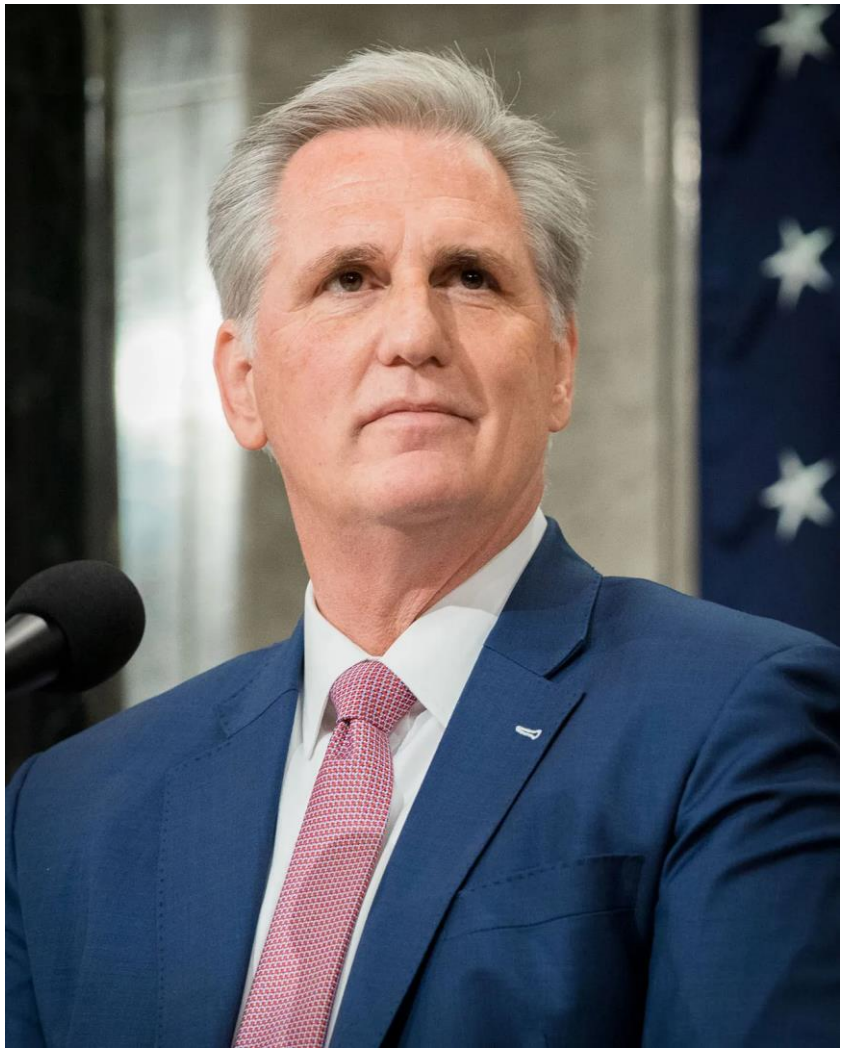
- Newly-elected House Speaker Kevin McCarthy, after his party denied him the leadership position over the course of five days and 14 votes.

HOUSE: Rs have 222 (218 is a majority)

SENATE: Ds have 51 seats

What's possible?

- Judicial appointments
- Investigations
- Debt ceiling (July?)
- Immigration
- Big Tech
- Lowering drug prices
- Marijuana banking



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Maverick Health Policy

Multiple Proposed Rules in 2023

The federal agencies are preparing to promulgate several final rules and are seeking industry guidance on these proposals:

Comment Deadline	Topic
January 31, 2023	Privacy rule about substance use disorder records (42 CFR Part 2 data) and alignment with HIPAA
February 3, 2023	Individual health plan market rules (2024 Notice of Benefit and Payment Parameters)
February 13, 2023	Medicare Advantage and Part D market rules (CY2024 Changes to MA/Part D Program)
March 13, 2023	Electronic Prior Authorization (ePA) Proposed Rule
March 21, 2023	CMS Attachments, eSignature, Prior Auth Standards

Basics of the Electronic Prior Authorization (ePA) Proposed Rule

On December 13, 2022, CMS released a 402-page proposed rule to automate prior authorization processes:

Goal of the New Rules	Streamline existing prior authorization processes; improve health data access and exchange and care coordination
Entities Impacted By The Rule	Medicare Advantage plans Medicaid and CHIP managed care plans and state programs Qualified Health Plans on Federally-Facilitated Exchanges Facilities / clinicians with Medicare interoperability requirements
Proposed Implementation Date	January 1, 2026
Comment Deadline	March 13, 2022

Special Policy Session: Exploring the Impact of the Electronic Prior Authorization (ePA) Proposed Rule

WEDNESDAY, FEBRUARY 15 | 1:00 – 2:00 P.M. EDT

Please join us for an informative webinar with guest speaker Julie Barnes.
Learn more about:

- Legislative and Regulatory Outlook for Health Plans for 2023
- Understanding the Electronic Prior Authorization (ePA) Proposed Rule and the Impact on Health Plans

To register, please visit: www.avalonhcs.com

CLOSING REMARKS

Barry Davis, Chief Growth Officer, Avalon

Thank you

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SAVE THE DATE

Special Policy Session: Exploring the Impact of the Electronic Prior Authorization – February 15 | 1:00 - 2:00 PM EDT

Avalon Webinar - April 4| 2:00 - 3:00 PM EDT

To register for our upcoming webinars, please visit: www.avalonhcs.com