From: Elena Saunders
Sent: Thursday, 1 October 2020 3:31 PM
To: Diabetes Subcommittee <[redacted]>
Cc: Tal Sharrock ([redacted]) <[redacted]>; Peter Murray <[redacted]>; Adam McRae <[redacted]>
Subject: PHARMAC urgent request for advice SGLT 2 inhibitors and GLP 1 agonists

Tēnā koutou Diabetes Subcommittee,

As you are aware, we are currently consulting on the proposal to fund empagliflozin (with and without metformin) and dulaglutide under proposed special authority criteria You can read the consultation (including the proposed special authority criteria) here;
https://www pharmac govt nz/news/consultation 2020-09 09 diabetes agents/

We have already received a wide variety of responses to this consultation, which will be invaluable in informing the Board's final decision on this proposal

There are a number of themes that have arisen in regards to the wording of the Special Authority criteria (available in the RFP document and copied at the end of this email), and I would very much appreciate your views on these Below are three topics for consideration – each with specific questions we would like you to consider.

Please note that I am still investigating whether we would be in a position to make changes based on each of the below themes under the legal terms of the RFP, and your advice will help with this assessment

1. **Co prescribing of SGLT-2 inhibitor and GLP 1 agonist**

Background:
The proposed special authority criteria specifically exclude the combination of the two medicines. This is based on the clinical data we have considered in support of these medicines, which did not allow concomitant use. PHARMAC has not received a funding application for the use of these two medicines in combination, and has not received any data or clinical advice to support this proposed combination. To date, none of the consultation feedback received has provided supporting evidence for this request, however, we are aware that some data exist to inform the combination use. Attached is a literature search conducted by PHARMAC staff in September 2020 on this topic

At our zoom meeting on 11 May 2020 we asked your advice on the number of patients likely to access treatment under the proposed special authority criteria. This advice indicated that, under the proposal, there would likely be a total "eligible" population of around 60,000 people, that approximately 80% of these people would access either of the medicines under these criteria (i.e. around 48,000 people), and that of these 90% would take a SGLT-2 inhibitor, with the remaining 10% taking a GLP-1 agonist. The record of this meeting is attached for your reference.

Questions to the Subcommittee:

1. Do you consider it would be **clinically reasonable to** allow co prescribing of a SGLT 2 inhibitor and a GLP 1 agonist?
    a. If yes, what evidence is available to support this? Please provide citations.
    b. If no, what additional evidence do you consider would be required in order to evaluate this?

2. Do you consider that there is sufficient evidence to demonstrate that the health benefit of the two agents in combination would be different to the clinical benefit of just adding the benefit observed by each individual agent together? Please provide citations.
3 If the special authority criteria were amended to allow co prescribing of a SGLT 2 inhibitor and a GLP 1 agonist, how would this change the patient number estimates previously provided?
    a. What proportion of the 48,000 patients do you consider would likely take both a SGLT-2 inhibitor and GLP-1 agonist concurrently?
    b. How would this change over time (e.g. would people commence first on one, and then add the other if control was suboptimal, or would people be likely to commence on both at the same time?)

2. Requirement for baseline anti-diabetic medicines

Background:
The proposed special authority criteria includes the requirement that the "patient has not achieved target HbA1c (of less than or equal to 53 mmol/mol) despite maximum tolerated doses of oral antidiabetic agents and/or insulin for at least 6 months". This criterion was left intentionally broad to allow for clinician judgement in what would be reasonable for an individual patient. On review of the consultation feedback, we consider it would be reasonable to provide further clarification on this criteria and seek your advice on appropriate wording. At this time we are not considering funding the use of empagliflozin or dulaglutide before an adequate trial of metformin, or to remove the HbA1c target.

PHARMAC staff propose the following, based on the feedback received;

> **Patient has not reached target HbA1c (of less than or equal to 53 mmol/mol, despite maximum tolerated dose of at least one oral hypoglycaemic agent (e.g. metformin) and/or insulin for 6 months or longer**

Questions to the Subcommittee:
1 Is the proposed wording for the baseline treatment criterion clinically appropriate and clear?
    a. If no, how do you propose it be amended to make the intent of the criteria clear to clinicians?

3. Use in paediatric patients with type 2 diabetes

Background:
The proposed special authority criteria have been developed to target high risk individuals, in line with the strongest clinical data The current wording includes 5 year cardiovascular risk as one method of defining this group. We are not aware of a validated lifetime risk calculator that is readily available for use in practice in New Zealand, including for use in children. We have received feedback from some stakeholders that the unmet need in paediatric type 2 diabetes (particularly in Māori and Pacific) may not be addresses by these criteria. We are also conscious that the strength and quantity of evidence for use in this group is limited and that empagliflozin (with and without metformin) is not approved by Medsafe for use in people under the age of 18, and we would anticipate the same is likely to apply for dulaglutide Our reading of international guidelines is that the views appear to be conflicting on this matter.
One respondent has proposed that if a criteria were included to allow the use of these medicines in people with type 2 diabetes diagnosed under the age of 16, that this would result in fewer than 20

additional people being eligible, but would serve to enhance . The respondent has not indicated whether this number represents incidence or prevalence, nor provided any data to support this. We therefore seek the Subcommittee's advice on this topic.

Questions to the Subcommittee:

1 Noting that SGLT 2 inhibitors and GLP 1 agonists are unapproved (or unlikely to be approved) for use in people under the age of 18, and considering international treatment guidelines, would it be clinically appropriate for a SGLT-2 inhibitors and/or GLP-1 agonists to be prescribed to people under that age of 18?
    a. Please provide citations for evidence to support this recommendation if appropriate
2 If the SA was amended to permit us in children under the age of 18 regardless of CVD risk, how many additional patients would you expect to be eligible each year (incident and prevalent)?
    a. What data sources are you aware of to inform an estimate of patient numbers for the paediatric type 2 diabetes population?
3 Do you support amendment of the proposed special authority criteria to enable use in paediatric patients?
    a If yes, what wording would you suggest?
    b. If yes, do you consider the prescriber types should be limited in any way?

I appreciate I am asking a lot of you, but your advice at this point in the process is incredibly helpful. If you are able to respond to me by **12 noon on Monday 5th October**, I would very much appreciate it.

If there is anything further I can provide to assist you in responding to these questions then please let me know Please also note you can claim for reimbursement for the time spend in providing this advice.

Ngā mihi nui,

Elena

Elena Saunders | Therapeutic Group Manager
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Proposed Special Authority criteria:

Initial application from any relevant practitioner.

Approvals valid without renewal for applications meeting the following criteria:

All of the following:
1. Patient has type 2 diabetes; and
2. Patient has not achieved target HbA1c (of ≤53 mmol/mol) despite maximum tolerated doses of oral antidiabetic agents and/or insulin for at least 6 months; and
3 Treatment is to be used in conjunction with other measures to reduce cardiovascular risk in line with current standard of care; and

4. Treatment will not be used in combination with a funded [SGLT-2 inhibitor/GLP-1 agonist] deleted as appropriate; and
5. Treatment must be used as an adjunct to oral antidiabetic therapy and/or insulin; and
6 Either:
    6.1. Patient has pre existing cardiovascular disease or risk equivalent*; or
    6 2 Patient has a 5-year absolute cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator; or
    6.3. Patient has diabetic kidney disease**

Note: *Defined as; prior cardiovascular disease event (ie angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia. ** Defined as: persistent albuminuria (albumin:creatinine ratio ≥ 3 mg/mmol, in at least two out of three samples over a 3-6 month period) and/or eGFR < 60 mL/min/1.73m2 in the presence of diabetes, without alternative cause.

From: Elena Saunders <Withheld under section 9(2)(a)>
Sent: Thursday, 1 October 2020 3:54 PM
To: Diabetes Subcommittee <Withheld under section 9(2)(a)>
Cc: Tal Sharrock <Withheld under section 9(2)(a)>; Peter Murray <Withheld under section 9(2)(a)>; Adam McRae <Withheld under section 9(2)(a)>
Subject: RE: PHARMAC urgent request for advice SGLT 2 inhibitors and GLP-1 agonists

And now with the attachment – sorry!

Elena Saunders | Therapeutic Group Manager

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PubMed, search terms: *((SGLT2 OR SGLT-2 OR empagliflozin OR dapagliflozin OR Ertugliflozin) AND (GLP1 OR GLP-1 OR exenatide OR liraglutide OR dulaglutide)) AND (combination OR concomitant)*
Also attached in the email are the full search results. I have pulled out the publications that appeared to be the most relevant. Have not included those for T1DM, in animals, and case reports, those not in English language.

Article + hyperlink	Citation	Abstract
Making a case for the combined use of SGLT2 inhibitors and GLP1 receptor agonists for cardiorenal protection	Sridhar VS, Dubrofsky L, Boulet J, Cherney DZ. Making a case for the combined use of SGLT2 inhibitors and GLP1 receptor agonists for cardiorenal protection. J Bras Nefrol. 2020 Sep 11:S0101-28002020005032204. English, Portuguese. doi: 10.1590/2175 8239-JBN-2020-0100. Epub ahead of print. PMID: 32926067.	Refused under section 18(d)

The effects of combination canagliflozin and glucagon-like peptide-1 receptor agonist therapy on intermediate markers of cardiovascular risk in the CANVAS program	Arnott C, Neuen BL, Heerspink HJL, Figtree GA, Kosiborod M, Lam CS, Cannon CP, Rosenthal N, Shaw W, Mahaffey KW, Jardine MJ, Perkovic V, Neal B. The effects of combination canagliflozin and glucagon like peptide 1 receptor agonist therapy on intermediate markers of cardiovascular risk in the CANVAS program. Int J Cardiol. 2020 Nov 1;318:126-129. doi: 10.1016/j.ijcard.2020.06.011. Epub 2020 Jun 20. PMID: 32569700.	Refused under section 18(d) [redacted]

Glucagon-like peptide-1 receptor agonists and sodium-glucose co-transporter-2 inhibitors as combination therapy for type 2 diabetes: A systematic review and meta-analysis	Mantsiou C, Karagiannis T, Kakotrichi P, Malandris K, Avgerinos I, Liakos A, Tsapas A, Bekiari E. Glucagon-like peptide-1 receptor agonists and sodium-glucose co-transporter-2 inhibitors as combination therapy for type 2 diabetes: A systematic review and meta-analysis. Diabetes Obes Metab. 2020 Jun 1. doi: 10.1111/dom.14108. Epub ahead of print. PMID: 32476254.	Refused under section 18(d)

Combining Glucagon-Like Peptide 1 Receptor Agonists and Sodium-Glucose Cotransporter 2 Inhibitors to Target Multiple Organ Defects in Type 2 Diabetes	Anderson JE. Combining Glucagon-Like Peptide 1 Receptor Agonists and Sodium-Glucose Cotransporter 2 Inhibitors to Target Multiple Organ Defects in Type 2 Diabetes. Diabetes Spectr. 2020 May;33(2):165 174. doi: 10.2337/ds19-0031. PMID: 32425454; PMCID: PMC7228816.	Refused under section 18(d) [redacted]

Effects of Glucagon-Like Peptide-1 Receptor Agonists, Sodium-Glucose Cotransporter-2 Inhibitors, and Their Combination on Endothelial Glycocalyx, Arterial Function, and Myocardial Work Index in Patients With Type 2 Diabetes Mellitus After 12-Month Treatment	Ikonomidis I, Pavlidis G, Thymis J, Birba D, Kalogeris A, Kousathana F, Kountouri A, Balampanis K, Parissis J, Andreadou I, Katogiannis K, Dimitriadis G, Bamias A, Iliodromitis E, Lambadiari V. Effects of Glucagon Like Peptide 1 Receptor Agonists, Sodium-Glucose Cotransporter-2 Inhibitors, and Their Combination on Endothelial Glycocalyx, Arterial Function, and Myocardial Work Index in Patients With Type 2 Diabetes Mellitus After 12-Month Treatment. J Am Heart Assoc. 2020 May 5;9(9):e015716. doi: 10.1161/JAHA.119.015716. Epub 2020 Apr 24. PMID: 32326806; PMCID: PMC7428590.	Refused under section 18(d)

GLP1 Receptor Agonist and SGLT2 Inhibitor Combination: An Effective Approach in Real-world Clinical Practice	Díaz-Trastoy O, Villar-Taibo R, Sifontes-Dubón M, Mozo-Peñalver H, Bernabeu-Morón I, Cabezas-Agrícola JM, Muñoz-Leira V, Peinó-García R, Martís-Sueiro A, García-López JM, Martínez-Olmos MA. GLP1 Receptor Agonist and SGLT2 Inhibitor Combination: An Effective Approach in Real-world Clinical Practice. Clin Ther. 2020 Feb;42(2):e1-e12. doi: 10.1016/j.clinthera.2019.12.012. Epub 2020 Jan 28. PMID: 32005534.	Refused under section 18(d)

The efficacy and safety of combinations of SGLT2 inhibitors and GLP-1 receptor agonists in the treatment of type 2 diabetes or obese adults: a systematic review and meta-analysis	Guo M, Gu J, Teng F, Chen J, Ma X, Chen Q, Pu Y, Jiang Z, Long Y, Xu Y. The efficacy and safety of combinations of SGLT2 inhibitors and GLP-1 receptor agonists in the treatment of type 2 diabetes or obese adults: a systematic review and meta-analysis. Endocrine. 2020 Feb;67(2):294-304. doi: 10.1007/s12020-019-02175-6. Epub 2020 Jan 3. PMID: 31900793.	Refused under section 18(d)

Efficacy and safety of GLP-1 receptor agonists as add-on to SGLT2 inhibitors in type 2 diabetes mellitus: A meta-analysis	Castellana M, Cignarelli A, Brescia F, Perrini S, Natalicchio A, Laviola L, Giorgino F. Efficacy and safety of GLP-1 receptor agonists as add-on to SGLT2 inhibitors in type 2 diabetes mellitus: A meta-analysis. Sci Rep. 2019 Dec 18;9(1):19351. doi: 10.1038/s41598-019-55524-w. PMID: 31852920; PMCID: PMC6920368.	Refused under section 18(d)

Effects of exenatide and open-label SGLT2 inhibitor treatment, given in parallel or sequentially, on mortality and cardiovascular and renal outcomes in type 2 diabetes: insights from the EXSCEL trial	Clegg LE, Penland RC, Bachina S, Boulton DW, Thuresson M, Heerspink HJL, Gustavson S, Sjöström CD, Ruggles JA, Hernandez AF, Buse JB, Mentz RJ, Holman RR. Effects of exenatide and open label SGLT2 inhibitor treatment, given in parallel or sequentially, on mortality and cardiovascular and renal outcomes in type 2 diabetes: insights from the EXSCEL trial. Cardiovasc Diabetol. 2019 Oct 22;18(1):138. doi: 10.1186/s12933-019-0942-x. PMID: 31640705; PMCID: PMC6805385.	Refused under section 18(d)

Combination therapy with SGLT-2 inhibitors and GLP-1 receptor agonists as complementary agents that address multi-organ defects in type 2 diabetes	Lajara R. Combination therapy with SGLT-2 inhibitors and GLP-1 receptor agonists as complementary agents that address multi-organ defects in type 2 diabetes. Postgrad Med. 2019 Nov;131(8):555-565. doi: 10.1080/00325481.2019.1670017. Epub 2019 Oct 3. PMID: 31580737.	Refused under section 18(d)

Hormone-substrate changes with exenatide plus dapagliflozin versus each drug alone: The randomized, active-controlled DURATION-8 study	Ferrannini E, Baldi S, Frías JP, Guja C, Hardy E, Repetto E, Jabbour SA, DeFronzo RA. Hormone-substrate changes with exenatide plus dapagliflozin versus each drug alone: The randomized, active-controlled DURATION-8 study. Diabetes Obes Metab. 2020 Jan;22(1):99-106. doi: 10.1111/dom.13870. Epub 2019 Oct 8. PMID: 31469220.	Refused under section 18(d)

Safety and Efficacy of Empagliflozin as Add-On Therapy to GLP-1 Receptor Agonist (Liraglutide) in Japanese Patients with Type 2 Diabetes Mellitus: A Randomised, Double-Blind, Parallel-Group Phase 4 Study	Terauchi Y, Utsunomiya K, Yasui A, Seki T, Cheng G, Shiki K, Lee J. Safety and Efficacy of Empagliflozin as Add-On Therapy to GLP-1 Receptor Agonist (Liraglutide) in Japanese Patients with Type 2 Diabetes Mellitus: A Randomised, Double-Blind, Parallel-Group Phase 4 Study. Diabetes Ther. 2019 Jun;10(3):951-963. doi: 10.1007/s13300-019-0604-8. Epub 2019 Mar 25. PMID: 30912033; PMCID: PMC6531579.	Refused under section 18(d)

Semaglutide once weekly as add-on to SGLT-2 inhibitor therapy in type 2 diabetes (SUSTAIN 9): a randomised, placebo-controlled trial	Zinman B, Bhosekar V, Busch R, Holst I, Ludvik B, Thielke D, Thrasher J, Woo V, Philis-Tsimikas A. Semaglutide once weekly as add-on to SGLT 2 inhibitor therapy in type 2 diabetes (SUSTAIN 9): a randomised, placebo-controlled trial. Lancet Diabetes Endocrinol. 2019 May;7(5):356-367. doi: 10.1016/S2213-8587(19)30066-X. Epub 2019 Mar 1. Erratum in: Lancet Diabetes Endocrinol. 2019 Mar 11;: Erratum in: Lancet Diabetes Endocrinol. 2019 Aug;7(8):e20. Erratum in: Lancet Diabetes Endocrinol. 2019 Nov;7(11):e22. PMID: 30833170.	Refused under section 18(d)

Combination Therapy With Glucagon-Like Peptide-1 Receptor Agonists and Sodium-Glucose Cotransporter 2 Inhibitors in Older Patients With Type 2 Diabetes: A Real-World Evidence Study	Carretero Gómez J, Arévalo Lorido JC, Gómez Huelgas R, García de Lucas D, Mateos Polo L, Varela Aguilar JM, Seguí Ripoll JM, Ena J; Diabetes, Obesity, and Nutrition Spanish Working Group. Combination Therapy With Glucagon Like Peptide-1 Receptor Agonists and Sodium-Glucose Cotransporter 2 Inhibitors in Older Patients With Type 2 Diabetes: A Real-World Evidence Study. Can J Diabetes. 2019 Apr;43(3):186-192. doi: 10.1016/j.jcjd.2018.09.001. Epub 2018 Sep 8. PMID: 30415909.	Refused under section 18(d)

SGLT-2 Inhibitors and Cardiovascular Protection: Lessons and Gaps in Understanding the Current Outcome Trials and Possible Benefits of Combining SGLT-2 Inhibitors With GLP-1 Agonists	Abdelgadir E, Rashid F, Bashier A, Ali R. SGLT-2 Inhibitors and Cardiovascular Protection: Lessons and Gaps in Understanding the Current Outcome Trials and Possible Benefits of Combining SGLT 2 Inhibitors With GLP 1 Agonists. J Clin Med Res. 2018 Aug;10(8):615-625. doi: 10.14740/jocmr3467w. Epub 2018 Jun 27. PMID: 29977418; PMCID: PMC6031247.	Refused under section 18(d)

Combination of SGLT-2 Inhibitors and GLP-1 Receptor Agonists: Potential Benefits in Surrogate and Hard Endpoints	Doumas M, Imprialos K, Stavropoulos K, Reklou A, Sachinidis A, Athyros VG. Combination of SGLT-2 Inhibitors and GLP-1 Receptor Agonists: Potential Benefits in Surrogate and Hard Endpoints. Curr Pharm Des. 2018;24(17):1879-1886. doi: 10.2174/1381612824666180604113653. PMID: 29865997.	Refused under section 18(d)

Combination Treatment of SGLT2 Inhibitors and GLP-1 Receptor Agonists: Symbiotic Effects on Metabolism and Cardiorenal Risk	**Goncalves E, Bell DSH. Combination Treatment of SGLT2 Inhibitors and GLP-1 Receptor Agonists: Symbiotic Effects on Metabolism and Cardiorenal Risk. Diabetes Ther. 2018 Jun;9(3):919-926. doi: 10.1007/s13300-018-0420-6. Epub 2018 Apr 5. PMID: 29623594; PMCID: PMC5984923.**	Refused under section 18(d) [redacted]

Effects of exenatide once weekly plus dapagliflozin, exenatide once weekly alone, or dapagliflozin alone added to metformin monotherapy in subgroups of patients with type 2 diabetes in the DURATION-8 randomized controlled trial		Refused under section 18(d)

Dulaglutide as add-on therapy to SGLT2 inhibitors in patients with inadequately controlled type 2 diabetes (AWARD-10): a 24-week, randomised, double-blind, placebo-controlled trial		Refused under section 18(d)

SGLT2 inhibitors and GLP-1 receptor agonists: a sound combination		No abstract available
Efficacy and safety of canagliflozin as add-on therapy to a glucagon-like peptide-1 receptor agonist in Japanese patients with type 2 diabetes mellitus: A 52-week, open-label, phase IV study		Refused under section 18(d) [redacted]

Effects of exenatide once weekly plus dapagliflozin, exenatide once weekly, or dapagliflozin, added to metformin monotherapy, on body weight, systolic blood pressure, and triglycerides in patients with type 2 diabetes in the DURATION-8 study		Refused under section 18(d)
Should We Be Combining GLP-1 Receptor Agonists and SGLT2 Inhibitors in Treating Diabetes?		Editorial. No abstract available.

Effect of Sodium Glucose Cotransporter 2 Inhibitors With Low SGLT2/SGLT1 Selectivity on Circulating Glucagon-Like Peptide 1 Levels in Type 2 Diabetes Mellitus		Refused under section 18(d)

Combination SGLT2 inhibitor and GLP-1 receptor agonist therapy: a complementary approach to the treatment of type 2 diabetes		Refused under section 18(d)

[The combination of GLP-1 analogs and SGLT2 inhibitors : new perspectives ?]		Refused under section 18(d) [redacted]
Combination therapy with GLP-1 receptor agonist and SGLT2 inhibitor		

Dapagliflozin once daily plus exenatide once weekly in obese adults without diabetes: Sustained reductions in body weight, glycaemia and blood pressure over 1 year		Refused under section 18(d)

Glucagon-like peptide-1 receptor agonists and sodium-glucose co-transporter-2 inhibitors: Sequential or simultaneous start?		No abstract available

Real-world effectiveness and safety of dapagliflozin therapy added to a GLP1 receptor agonist in patients with type 2 diabetes		Refused under section 18(d) [redacted]

Combination therapy with GLP-1 analogues and SGLT-2 inhibitors in the management of diabesity: the real world experience		Refused under section 18(d) [redacted]

Exenatide once weekly plus dapagliflozin once daily versus exenatide or dapagliflozin alone in patients with type 2 diabetes inadequately controlled with metformin monotherapy (DURATION-8): a 28 week, multicentre, double-blind, phase 3, randomised controlled trial		Refused under section 18(d)

Dapagliflozin once-daily and exenatide once-weekly dual therapy: A 24-week randomized, placebo-controlled, phase II study examining effects on body weight and prediabetes in obese adults without diabetes		Refused under section 18(d) [redacted]

Combination therapy of SGLT2 inhibitors with incretin-based therapies for the treatment of type 2 diabetes mellitus: Effects and mechanisms of action		Refused under section 18(d) [redacted]

Empagliflozin and linagliptin combination therapy for treatment of patients with type 2 diabetes mellitus		Refused under section 18(d) [redacted]

SGLT-2 INHIBITOR THERAPY ADDED TO GLP-1 AGONIST THERAPY IN THE MANAGEMENT OF T2DM		Refused under section 18(d) [redacted]

Dapagliflozin as monotherapy or combination therapy in Japanese patients with type 2 diabetes: an open-label study		Refused under section 18(d)

From: Withheld under section 9(2)(g)(i)
Sent: Monday, 5 October 2020 11:41 am
To: Elena Saunders <Withheld under section 9(2)(a)>
Subject: RE: PHARMAC urgent request for advice SGLT 2 inhibitors and GLP 1 agonists

Dear Elena,

Thanks for this. Haven't had a lot of time to look as I have been on for the wards.

Others would be better place to comment on points 1 and 2.

In relation to point 3 – you may recall we had exactly this discussion at the sub-committee meeting (in terms of lifetime risk and the fact that the cardiovascular risk calculators don't take early age onset patients into account y they clearly have high risk). So yes would definitely support extending access to youth with T2D who aren't achieving glycaemic targets, as that is really the only measure that we have You could also include microalbuminuria (with a albumin excretion rate definition)

I would suggest limiting the Special authority to endocrinologists or diabetes physicians or paediatric endocrinologists/general paediatricians with a diabetes special interest (we could let you know who those are around the country) In terms of numbers, Auckland probably has the best data, at least for under 16s (not so sure for the 16 18 year olds or >18s), on their database and could probably give you a reasonably accurate number. In Wellington I have about 5-6 patients in whom I would consider an SGLT 2 9almost certainly first) or possibly a GLP 1 agonist (second) because they are not meeting glycaemic targets and/or have additional risk factors for renal complications….so I would certainly agree that the numbers would not be large That would include all the patients in Wellington under 16 with type 2 diabetes and some in the 16-17 age range 9as I keep seeing them sometimes if they are still at school).

Hope that helps.

Cheers,
Withh

From: Elena Saunders <Withheld under section 9(2)(a)>
Sent: Monday, 5 October 2020 3:41 PM
To: Withheld under section 9(2)(g)(i)
Subject: RE: PHARMAC - urgent request for advice SGLT 2 inhibitors and GLP 1 agonists

Thanks With for this – very helpful

Do you think it would be reasonable to have a 16 years or younger at time of diagnosis criterion? I am finding it difficult to find a clear definition of paediatric onset T2DM. If you have a definition you can point me to that would be really helpful

Thanks,

Elena

Elena Saunders | Therapeutic Group Manager

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From: Withheld under section 9(2)(g)(i)
Sent: Tuesday, 6 October 2020 10:01 am
To: Elena Saunders <Withheld under section 9(2)(a)>
Subject: RE: PHARMAC urgent request for advice SGLT 2 inhibitors and GLP 1 agonists

Thanks Elena,

I doubt there would be a definition of paediatric onset T2D, but the UN convention on the rights of the child defines a child as 17 years or under.....so that may be a starting point?

Cheers,
Withh

PS I'm happy with the wording for point 2....I guess the only question would be whether you want them to have tried an oral agent in addition to Metformin.

Cheers,
Withh

From: Elena Saunders
Sent: Monday, 5 October 2020 3:38 pm
To: Diabetes Subcommittee <Withheld under section 9(2)(a)>
Cc: 'Tal Sharrock (Withheld under section 9(2)(a))' <Withheld under section 9(2)(a)>; Peter Murray <Withheld under section 9(2)(a)>; Adam McRae <Withheld under section 9(2)(a)>
Subject: RE: PHARMAC urgent request for advice SGLT 2 inhibitors and GLP 1 agonists

Tēnā koutou,

Thanks to the two members who have responded. We would really appreciate additional feedback on these important points if you are able to respond in the next day or so

Elena

Elena Saunders | Therapeutic Group Manager

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From: Withheld under section 9(2)(g)(i)
Sent: Monday, 5 October 2020 4:32 pm
To: Elena Saunders <Withheld under section 9(2)(a)>; Diabetes Subcommittee <Withheld under section 9(2)(a)>
Cc: Tal Sharrock <Withheld under section 9(2)(a)>; Peter Murray <Withheld under section 9(2)(a)>; Adam McRae <Withheld under section 9(2)(a)>
Subject: Re: PHARMAC urgent request for advice SGLT 2 inhibitors and GLP 1 agonists

Dear Elena and all

My apologies for my delay in responding to this as I have returned to a very full inbox today and whilst I have been working on it all day, I have been hampered by a few other meetings!

My comments are below in blue:

Questions to the Subcommittee:

4. Do you consider it would be **clinically reasonable to** allow co-prescribing of a SGLT-2 inhibitor and a GLP 1 agonist?
    a. If yes, what evidence is available to support this? Please provide citations.

Yes, multiple glucose lowering agents are required for the management of type 2 diabetes, with these two classes being recognised as most appropriate to be used in combination due to their different mechanism of action to produce a reduction in HbA1c. Only the GLP1RA and DPP4i should not be used together due to their related mechanisms of action meaning that the effect of the DPP4i is redundant once a GLP1RA is added. The health benefit of these two classes in particular when used in combination includes additive glucose lowering, with advantages of weight loss, lack of hypos, lower BP, meaning that this combination treatment is more acceptable and easier for people living with type 2 diabetes than other combinations involving sulfonylureas or insulin for example. These two agents in combination feature in the ADA treatment guidelines algorithm fig 9.1
https://care.diabetesjournals.org/content/43/Supplement_1/S98
and the Australian guidelines
https://diabetessociety.com.au/documents/ADS_POSITIONSTATEMENT_v2.4.pdf

    b. If no, what additional evidence do you consider would be required in order to evaluate this?

5. Do you consider that there is sufficient evidence to demonstrate that the health benefit of the two agents in combination would be different to the clinical benefit of just adding the benefit observed by each individual agent together? Please provide citations

Studies are currently underway to determine whether this combination provides synergistic (rather than additive) effects to reduce macro and microvascular complications, although the review paper attached indicates this is very likely.

6 If the special authority criteria were amended to allow co prescribing of a SGLT 2 inhibitor and a GLP-1 agonist, how would this change the patient number estimates previously provided?

What proportion of the 48,000 patients do you consider would likely take both a SGLT 2 inhibitor and GLP-1 agonist concurrently?
Please see https://care diabetesjournals org/content/early/2020/02/10/dc19 1943

https://journals plos org/plosone/article?id=10 1371/journal pone 0229621
This describes the initiation of SGLT2i and GLP1RA in USA and Europe.

For rationing/maximal cost-effectiveness purposes, continuation of GLP1RA (when used in combination with SGLT2i) could be recommended only if 10mmol/mol reduction in HBA1c and >=3% weight loss is achieved after 6 months (as per NICE 2018) rather than an open indication on the basis of CVD risk reduction/renal protection which is afforded by either agent when used on its own This does add complexity to the SA though.

a. How would this change over time (e.g. would people commence first on one, and then add the other if control was suboptimal, or would people be likely to commence on both at the same time?)

Most people would commence on SGLT2i first and only add the GLP1RA if the control was suboptimal

Questions to the Subcommittee:

2. Is the proposed wording for the baseline treatment criterion clinically appropriate and clear?
    a. If no, how do you propose it be amended to make the intent of the criteria clear to clinicians?

Patient has not reached target HbA1c (of less than or equal to 53 mmol/mol), despite maximum tolerated dose of at least one oral hypoglycaemic agent (e.g. metformin) and/or insulin for 6 months or longer

- Yes this is much clearer than before.

Questions to the Subcommittee:

4. Noting that SGLT 2 inhibitors and GLP 1 agonists are unapproved (or unlikely to be approved) for use in people under the age of 18, and considering international treatment guidelines, would it be clinically appropriate for a SGLT-2 inhibitors and/or GLP 1 agonists to be prescribed to people under that age of 18?
    a. Please provide citations for evidence to support this recommendation if appropriate

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5792816/pdf/cpe-27-001.pdf
https://care diabetesjournals.org/content/39/3/323

I only see young people with diabetes once they are above the age of 16 in my adolescent diabetes clinic, so paediatricians on the panel may wish to comment on this further, but among young adults aged 16-25, the benefits of SGLT2i and GLP1RA is marked as this population benefits most from combination medications without the critical requirement to test capillary blood glucose levels or potential for hypoglycaemia or weight gain, given the competing demands of this age group who are most vulnerable to poor outcomes at a young age In my view there is not much difference physiologically between aged 16 vs 18 years and rather than this arbitrary threshold, I would consider that these drugs are safe and efficacious at all ages Until the PK and PD studies are completed for paediatric patients and phase 3 studies (currently underway for several of these) since the white paper was published in Diabetes Care 2016 we won't be able to have this in guidelines of care.

5. If the SA was amended to permit us in children under the age of 18 regardless of CVD risk, how many additional patients would you expect to be eligible each year (incident and prevalent)?
    a What data sources are you aware of to inform an estimate of patient numbers for the paediatric type 2 diabetes population?

https://pubmed.ncbi.nlm.nih.gov/29689124/

Also [redacted] is doing a PhD on young adult type 2 diabetes so may have some national figures on those aged 15 18. As an estimate of those aged 16 25 with diabetes in [redacted] there were 550, but this number is driven predominantly by those aged 18-25 given the higher prevalence by age (email [redacted])

6. Do you support amendment of the proposed special authority criteria to enable use in paediatric patients?
    a. If yes, what wording would you suggest?
    b. If yes, do you consider the prescriber types should be limited in any way?

Yes, youth with type 2 diabetes would benefit greatly but I cannot think of a way to include these in the special authority criteria without seeming ageist Open access would transfer the burden of appropriate prescribing to the prescribers!

Hope this helps and keen to hear what the feedback was from others also.

Kind regards
[redacted]

From: Withheld under section 9(2)(g)(i)
Sent: Tuesday, 6 October 2020 11:50 am
To: Elena Saunders <Withheld under section 9(2)(a)>
Subject: RE: PHARMAC urgent request for advice SGLT 2 inhibitors and GLP 1 agonists

Kia ora Elena, have gone with a (relatively) rapid turnaround time and imperfect wording, rather than 'academic perfection', with my reply. Please feel free to get back if what I've written is unclear or makes no sense.

Ngā mihi nui, Withheld under
Withheld under

Questions to the Subcommittee:

1. Do you consider it would be clinically reasonable to allow co prescribing of a SGLT 2 inhibitor and a GLP-1 agonist? yes
    a If yes, what evidence is available to support this? Please provide citations Would think that the most likely pragmatic reason to use a combination of agents will be for patients concerned about weight gain on insulin, but also note the improvement in other metabolic parameters when using this combination: https://pubmed.ncbi.nlm.nih.gov/31852920/. Also, occupational drivers, or similar, who are concerned about work related hypoglycaemia, are likely to want to avoid insulin and sulphonylureas. In other words, after starting on an SGLT2i and finding that glycaemic targets are not reached, many patients with type 2 diabetes might prefer a GLP1 RA to insulin. I accept that these metabolic improvements con combined therapy might be viewed as intermediate endpoints and we have no long term CV or renal outcome studies of the combination of therapies, however this general approach is I believe compatible with ADA guidelines e.g. https://care diabetesjournals org/content/diacare/43/Supplement 1/S98/F1 large.j pg
    b If no, what additional evidence do you consider would be required in order to evaluate this?
2. Do you consider that there is sufficient evidence to demonstrate that the health benefit of the two agents in combination would be different to the clinical benefit of just adding the benefit observed by each individual agent together? Please provide citations. Sorry your question does not make sense to me – it seems to imply that you are looking for a synergistic, rather than additive benefit (?), so am probably answering a different question to the one posted by you: *There might be an assumption that the body weight advantages of using a combination of these medications that does not include insulin (or includes insulin at low dose), would have secondary physical and psychological benefits*.
3 If the special authority criteria were amended to allow co prescribing of a SGLT 2 inhibitor and a GLP-1 agonist, how would this change the patient number estimates previously provided?
    a. What proportion of the 48,000 patients do you consider would likely take both a SGLT-2 inhibitor and GLP-1 agonist concurrently? Assuming that the funded GLP 1RA would be an injectable, then most clinicians would prescribe a tablet first of all i.e. they would prescribe an SGLT2i, before a GLP-1RA. I suspect that clinicians / practitioners will be overwhelmed by the number of patients eligible for these agents, so roll out of combination therapy would be slow. Also, there are associated complexities of prescribing these agents compared to prescribing a DPP4i e g back-titration of insulin dose may be complex and the side effect profile needs to be explained to patients in detail, to encourage ongoing adherence. This will take up so much in the way of clinical resource that adding in a GLP1 RA near-concurrently will present clinicians with logistic capacity difficulties (especially as PHARMAC are likely to fund an *injectable* GLP1 RA) The number of eligible patients taking up combination therapy in the first year may be therefore be low – maybe only 10% of those starting an SGLT2i?
    b. How would this change over time (e.g. would people commence first on one, and then add the other if control was suboptimal, or would people be likely to commence on both at the same time?) As clinical confidence is gained, would expect more uptake of combination therapy in a couple of sequential steps ie SGLT2i then GLP1 RA maybe a few months later if HbA1c targets are not met, with commencement of the combination together (or maybe a few weeks apart), being done only when there is a high level of provider comfort, which in turn would be

gained from clinical experience over time. Also, as clinical educational skills are gained in teaching how to use an injectable GLP1 RA, with minimal clinical resources, then this might become a more popular first line adjunctive agent, in part because of its greater weight loss effects

Questions to the Subcommittee:

4. Is the proposed wording for the baseline treatment criterion clinically appropriate and clear? No
    a If no, how do you propose it be amended to make the intent of the criteria clear to clinicians? I think some wording about lifestyle change should be included. If a patient is metformin intolerant, then the wording as it stands might encourage the use of a very small amount of say a sulphonylurea, acarbose or insulin, maybe merely 'for the paperwork or 'for show', not with full therapeutic intent Acknowledging that it is easy to stay within the 'letter' but not the intent of the current wording i.e. a clinical workaround is easy, I think PHARMAC should aim for very permissive wording and encourage clinicians to use common sense, not a clinical work around. Maybe start with a preamble – *PHARMAC considers that metformin remains the first line glucose lowering agent for type 2 DM in Aotearoa / NZ, for those who have no contraindications to its use and can tolerate it*.

An SGLT2i or GLP1-RA may be introduced, with a view to long term prescribing, if:

- *The patient continues with lifestyle change*
- *And has an HbA1c in the last three months ≥ 53mmol/mol*
- *And continues to be prescribed one or more 'standard' antidiabetic medications such as metformin and/or insulin, in a clinically appropriate dose*
- *And has been on one or more 'standard' antidiabetic medications for a minimum of six months in the period immediately prior to commencement on a SGLT2i and /or GLP1 RA*
- *Or has documentation of contraindications or side effects to standard anti-diabetic therapies, which in the opinion of the prescriber would make it clinically unreasonable to continue with these agents, or to re introduce these agents in patients who have previously been intolerant to these agents*

While wording like this is very long-winded, clinicians would get their 'head around' *intent*, reasonably quickly, then not need to look this up in the long term.

Questions to the Subcommittee:

1 Noting that SGLT 2 inhibitors and GLP 1 agonists are unapproved (or unlikely to be approved) for use in people under the age of 18, and considering international treatment guidelines, would it be clinically appropriate for a SGLT 2 inhibitors and/or GLP 1 agonists to be prescribed to people under that age of 18? Yes, on 'compassionate' grounds e.g. young patients who are not responding to current clinical advice and management and who in the opinion of their attending clinician, have a poor medium term prognosis on their current treatment regimen.
    a. Please provide citations for evidence to support this recommendation if appropriate There are several published case reports of the use of 'off label' agents in dire clinical situations and I would image that this would be the setting in which NZ physicians would choose to use these agents.
2. If the SA was amended to permit use in children under the age of 18 regardless of CVD risk, how many additional patients would you expect to be eligible each year (incident and prevalent)? Minimal – maybe <30 in the first year of prescribing and maybe a prevalence of <100
    a. What data sources are you aware of to inform an estimate of patient numbers for the paediatric type 2 diabetes population? Publications such as

https://pubmed.ncbi.nlm.nih.gov/29689124/ help inform total population numbers, but a quick discussion with paediatric diabetes nurses from around the country is also likely to provide a 'head count' of the number of patients with 'extreme' refractory type 2 diabetes under their care, or who are known to them if 'lost to follow up'.

3. Do you support amendment of the proposed special authority criteria to enable use in paediatric patients? yes
    a. If yes, what wording would you suggest? Maybe something along these lines: These medications are not registered for use in children and adolescents aged <18 years and there are no studies available to inform prescribers about the impact of these medications on children's growth and development Prescribing in this setting should therefore be considered 'off label'.
    b If yes, do you consider the prescriber types should be limited in any way? Yes, under specialist guidance

From: Elena Saunders [Withheld under section 9(2)(a)]
Sent: Wednesday, 7 October 2020 9:11 a.m.
To: Withheld
Subject: RE: PHARMAC - urgent request for advice - SGLT-2 inhibitors and GLP-1 agonists[EXTERNAL SENDER]
Kia ora Withhel,

Thank you for the time on the phone yesterday. Just confirming the things we discussed;

- If used together, you consider it unlikely there would be any synergistic effect for SGLT 2 inhibitor with GLP 1 RA
    - The effect is more likely to be less than additive with respect to cardio-renal outcomes
    - This view is informed be data from other primary and secondary cardiovascular prevention medications
- Within the context of real life diabetes management (rather than the somewhat artificial environment of RCTs that might aim for HbA1c equivalency between treatment and control arms), then you might get the most 'bangs for your buck' in term
- If we were to allow the use of SGLT-2 and GLP-1 together you consider that;
    - Uptake of the GLP-1 in addition to an SGLT-2 is likely to be slow, based predominantly on system constraints
    - Despite significant unmet need, you estimate roughly 10% of those taking an SGLT-2 inhibitor would also take a GLP-1 agonist in combination
    - It would be reasonable to expect a 3 month trial on a SGLT-2 prior to adding a GLP 1, with access based on a repeat HbA1c for example

Can you let me know if I've misunderstood any of the above?

Thanks!

Elena

Elena Saunders | Therapeutic Group Manager

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From: Withheld under section 9(2)(g)(i)
Sent: Wednesday, 7 October 2020 12:02 pm
To: Elena Saunders <Withheld under section 9(2)(a)>
Subject: FW: PHARMAC - urgent request for advice - SGLT-2 inhibitors and GLP-1 agonists[EXTERNAL SENDER]

Thanks Elena - yes you managed to capture our telephone conversation very well. Hope you don't mind me adding a few additional comments (see the red typing below, added to your previous e-mail). Obviously this response is largely just 'crystal ball gazing' personal opinion. Also, because my first 'red paragraph' answer below may not be clear, have added an abstract that provides another way of looking at things:

The Law of Diminishing Returns in Clinical Medicine: How Much Risk Reduction Is Enough?
The law of diminishing returns, first described by economists to explain why, beyond a certain point, additional inputs produce smaller and smaller outputs, offers insight into many situations encountered

in clinical medicine. For example, when the risk of an adverse event can be reduced in several different ways, the impact of each intervention can generally be shown mathematically to be reduced by the previous ones. The diminishing value of successive interventions is further reduced by adverse consequences (eg, drug-drug, drug-disease, and drug nutrient interactions), as well as by the total expenditures of time, energy, and resources, which increase with each additional intervention. It is therefore important to try to prioritize interventions based on patient-centered goals and the relative impact and acceptability of the interventions. We believe that this has implications for clinical practice, research, and policy.

Ngā mihi, Withhe

Thank you for the time on the phone yesterday. Just confirming the things we discussed;

- If used together, you consider it unlikely there would be any synergistic effect for SGLT 2 inhibitor with GLP 1 RA
    - The effect is more likely to be less than additive with respect to cardio renal outcomes
    - This view is informed be data from other primary and secondary cardiovascular prevention medications

Within the context of real life diabetes management (rather than the somewhat artificial environment of RCTs that might aim for HbA1c equivalency between treatment and control arms), then you usually get the most 'bangs for your buck' in terms of glucose lowering effect and impact on complications such as kidney disease, when treating patients who are clearly sub optimally controlled. When glycaemic control is at or near glycaemic 'target', then adding in another anti glycaemic agent will have less of an impact on risk of developing complications Also, the concept of relative versus absolute risk means that when you improve absolute risk (e.g. cardio renal risk) in a patient with the use of one medication, then adding in another agent to what is now a 'lower risk' individual, will have less of an impact on outcomes.

- If we were to allow the use of SGLT 2 and GLP 1 together you consider that;
    - Uptake of the GLP 1 in addition to an SGLT 2 is likely to be slow, based predominantly on system constraints Yes, certainly within the next year I believe most diabetes health delivery systems are already at full capacity, so there will be ongoing 'therapeutic inertia'
    - Despite significant unmet need, you estimate roughly 10% of those taking an SGLT 2 inhibitor would also take a GLP 1 agonist in combination As above, the 2 agents both have significant side effect profiles, therefore patient expectations around risk and benefit 'needs managing' for optimal overall clinical management, so this will slow uptake. Also an injectable product requires quite a bit of patient educational resource, when used in the high risk and vulnerable populations that these drugs are targeted at.
    - It would be reasonable to expect a 3 month trial on a SGLT 2 prior to adding a GLP-1, with access based on a repeat HbA1c for example. Yes. The impact of SGLT2i on glycaemic control, is seen quite quickly. There will always be clinical exceptions to the general approach of adding in the first agent, then waiting three months before adding in the second agent e.g. someone with a very high basline HbA1c who is refusing to take insulin, is inevitably going to need two agents, but most patients will 'tolerate' three months between the addition of the first and second agent.

-----Original Message-----
From: [redacted]
Sent: Monday, 12 October 2020 5:32 PM
To: [redacted] Elena Saunders
<[redacted]>
Subject: Meeting with Pharmac

[redacted] is inviting you to a scheduled Zoom meeting.

Topic: Meeting with Pharmac
Time: Oct 14, 2020 05:30 PM Auckland, Wellington

Join Zoom Meeting
https://us02web zoom us/j/[redacted]

Meeting ID: [redacted]

From: Elena Saunders
Sent: Wednesday, 14 October 2020 10:22 am
To: [redacted]
Cc: Peter Murray <[redacted]>; Scott Metcalfe
<[redacted]>; Bill Kaua <[redacted]>
Subject: RE: Meeting with Pharmac

Tēnā tātou,

Thank you for making the time to meet this evening

In advance of our hui, I wanted to let you know that based on the valuable consultation we have received from a wide range of stakeholders we are in the process of considering amendments to the proposed Special Authority criteria.

While acknowledging these do not go to the lengths you have proposed in your feedback, we would very much appreciate the opportunity this evening (if time permits) to explain our rationale, and seek your feedback on our current working draft copied below. Please note this is provided as commercial in confidence information we would appreciate it if you did not share these draft criteria more broadly.

Special Authority for Subsidy
Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:
All of the following:

1 Patient has type 2 diabetes; and
2 Any of the following:
    2 1 Patient has pre existing cardiovascular disease or risk equivalent*; or
    2 2 Patient has an absolute 5-year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator**; or
    2 3 Patient has diabetic kidney disease***; and
3. Patient has not achieved target HbA1c (of less than or equal to 53 mmol/mol) despite maximum tolerated dose of at least one blood glucose lowering agent (eg metformin hydrochloride) for at least 6 months; and
4 Treatment is to be used in conjunction with other measures to reduce cardiovascular risk in line with current standard of care; and
5 Treatment will not be used in combination with a funded GLP 1 agonist/SGLT 2 inhibitor (deleted as appropriate); and
6. Treatment must be used as an adjunct to oral antidiabetic therapy and/or insulin

Note:
*Defined as: prior cardiovascular disease event (i.e. angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia.
** If, due to the patient's young age at diagnosis, the use of a 5-year cardiovascular risk according to a validated risk calculator is not appropriate, but the patient is at a high lifetime risk of cardiovascular or renal complications, this cardiovascular risk assessment criterion can be completed based on the opinion of the treating clinician.
***Defined as: persistent albuminuria (albumin:creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3-6 month period) and/or eGFR less than 60 mL/min/1.73m2 in the presence of diabetes, without alternative cause.

I also wanted to ensure you had seen the recent publication in NZMJ (attached)

If you have any questions prior to this evening then please let me know. Otherwise, I look forward to our kōrerorero then.

Ngā mihi nui,

Elena

Elena Saunders (she/her) | Therapeutic Group Manager
_____
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PHARMAC
TE PĀTAKA WHAIORANGA

FILE NOTE

Subject:	Hui with Te Rōpū Whakakaupapa Urutā
Event Type:	Meeting
Author:	Elena Saunders
Attendees:	Te Rōpū Whakakaupapa Urutā (TRWU): Withheld under section 9(2)(g)(i) Te Pātaka Whaioranga PHARMAC: Elena Saunders (TGM) - Dr Scott Springford-Metcalfe (Chief Advisor Population Medicine/DMD) - Dr Peter Murray (DMD) Wiremu Kaua (Kaumātua to Te Pātaka Whaioranga PHARMAC)
Location:	Zoom
Date event took place:	14 October 2020 5:30pm

Discussion:

TRWU greeted TPW. TRWU thanked TPW for the opportunity to meet and discuss. TPW thanked TRWU for their well considered feedback and the opportunity to meet with them

Attendees discussed the diabetes RFP noting the following;

Māori are disproportionately affected by type 2 diabetes, and rely on a healthcare system that is systemically inequitable for Māori This is unacceptable

Open listing for the two new medicines is not achievable within the budget available

- TPW did not engage directly with Māori in the development of the proposal in a way that would have upheld the Te Tiriti principles

TPW considers it used an equity lens when developing this proposal

TRWU consider that TPW did not consider equity when developing this proposal on the basis that Māori, and Pacific people, are at an inherently higher risk of CV and renal complications in comparison to Pākeha. TRWU condier that TPW does not have the equity capability to adequately consider this. TRWU consider that the funding of PD L1 inhibitors for melanoma and not for lung is an example where funding is implicitly based on ethnicity, and that this is an example of systemic racism towards Māori. TRWU maintained their position that, if open access can't be achieved for the diabetes medicines then an equity criterion specifically enabling access for Māori should be added Some members of TRWU considered this would be preferable to open listing as it would be an active action, rather than a passive one. TRWU consider that other changes proposed by TPW are minor adjustments that will have no meaningful impact on health equity for Māori TRWU noted a preference to delay listing in order to get this right TPW noted that considering the addition of a Māori-specific criterion would be a significant policy decision for TPW, and that this would take time to adequately work through and consider.

TPW asked about partnering with this group in future. TRWU noted they are working on a pro bono basis, and the future of this group was uncertain. TRWU would welcome financial support from TPW to continue its work TRWU offered help to support TPW in developing its approach to equity, including building the case for a Māori-specific criterion. TRWU would be willing to champion this internally and externally.

There was not time to discuss the monitoring and implementation activities that were being proposed.

From: Elena Saunders <[redacted]>
Sent: Tuesday, 13 October 2020 12:51 PM
To: Diabetes Subcommittee <[redacted]>
Cc: Peter Murray <[redacted]>; Adam McRae <[redacted]>
Subject: FW: PHARMAC additional request for advice regarding Special Authority criteria[EXTERNAL SENDER]

Kia ora Diabetes Subcommittee,

I am sorry to bother you again but I am hoping you can help with some additional question related to the proposed Special Authority criteria for empagliflozin (with and without metformin) and dulaglutide

Based on the feedback to the consultation, and your valuable input to date, we are considering the following criteria (please ignore any formatting errors) The change I am now seeking your feedback on is highlighted in yellow, and is intended to enable access to youth with type 2 diabetes at high lifetime risk of complications

Special Authority for Subsidy
Initial application from any relevant practitioner Approvals valid without further renewal unless notified for applications meeting the following criteria:
All of the following:

7 Patient has type 2 diabetes; and
8 Any of the following:
  8 1 Patient has pre existing cardiovascular disease or risk equivalent*; or
  8 2 Patient has an absolute 5 year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator**; or
  8 3 Patient has diabetic kidney disease***; and
9 Patient has not achieved target HbA1c (of less than or equal to 53 mmol/mol) despite maximum tolerated dose of at least one blood glucose lowering agent (eg metformin hydrochloride) for at least 6 months; and
10 Treatment is to be used in conjunction with other measures to reduce cardiovascular risk in line with current standard of care; and
11 Treatment will not be used in combination with a funded GLP 1 agonist/SGLT 2 inhibitor (deleted as appropriate); and
12. Treatment must be used as an adjunct to oral antidiabetic therapy and/or insulin

Note: *Defined as: prior cardiovascular disease event (i e angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia
** If due to the patient's young age at diagnosis the use of a 5-year cardiovascular risk according to a validated risk calculator is not appropriate, but the patient is at a high lifetime risk of cardiovascular or renal complications, this cardiovascular risk assessment criterion can be completed based on the opinion of the treating clinician.
***Defined as: persistent albuminuria (albumin:creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3-6 month period) and/or eGFR less than 60 mL/min/1.73m2 in the presence of diabetes, without alternative cause.

Questions to the Subcommittee:

1. **Are the proposed criteria above clear from a clinical perspective?**
2. **Considering the additional text highlighted in yellow, how many additional people per year do you consider would access these medicines compared to the counterfactual where this text was not added?**

Elena Saunders | Therapeutic Group Manager

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From: Withheld under section 9(2)(g)(i)
Sent: Tuesday, 13 October 2020 1:12 pm
To: Elena Saunders <Withheld under section 9(2)(a)>
Subject: RE: PHARMAC additional request for advice regarding Special Authority criteria[EXTERNAL SENDER]

Thanks Elena,

I'd take the highlighted (yellow) wording to include young adults, not 'just' youth. Within this context, this wording looks clear to me. This wording would include vulnerable subpopulations, with vulnerability often being defined by ethnic background and / or social deprivation.

My guess is that clinicians would start cautiously in these subgroups (as clinical trials generally exclude these subgroups, so there is limited direct clinical trial information to inform usage). As clinical experience and confidence is gained, then numbers would increase. The sad reality is that these subgroups are frequently non adherent to medication so there will be a gap between 'total eligible' population and the population that receives long term treatment. Maybe <5,000 patients over 5 years?

Sorry I did not comment earlier but re: *Defined as: persistent albuminuria (albumin:creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3 6 month period) and/or eGFR less than 60 mL/min/1.73m2 in the presence of diabetes, without alternative cause.* The reality is that in type 2 diabetes, we might only screen the urine every year or so. There seems little point on wasting patient and laboratory resources, by insisting on a on a 3-6 month screening period in patients who have already demonstrated persistent microalbuminuria / proteinuria Maybe say: *a minimum of two out of three consecutive urine samples, within the last 5 years?*

Also, I think it was pointed out at our previous face to face meeting that the reference range for urinary albumin / creatinine ratio is gender specific. I personally think the proposed criteria are generous so am happy with the 3 mg/mmol , but others might want gender specific cut offs

Ngā mihi,

Withhe

From: Withheld under section 9(2)(g)(i)
Sent: Tuesday, 13 October 2020 3:24 pm
To: Elena Saunders <Withheld under section 9(2)(a)>
Subject: Re: FW: PHARMAC - additional request for advice regarding Special Authority criteria

I think this would cover the youngsters and about 100 maybe.

With

From: Withheld under section 9(2)(g)(i)
Sent: Wednesday, 14 October 2020 9:32 pm
To: Elena Saunders <Withheld under section 9(2)(a)>; Diabetes Subcommittee <Withheld under section 9(2)(a)>
Cc: Peter Murray <Withheld under section 9(2)(a)>; Adam McRae <Withheld under section 9(2)(a)>
Subject: Re: PHARMAC additional request for advice regarding Special Authority criteria

Kia ora Elena and all
This is a welcome addition to the access criteria however, I think the wording below will cause confusion amongst prescribers as to what the definition of young age at diabetes onset means I would suggest specifying this to be younger than age 25 or 30 when diagnosed with Type 2 diabetes, since the PREDICT cohort for CVD risk prediction excludes those younger than 30 From the VDR, the number of people with diabetes between the age of 15 24 is 4000, and the number of people with diabetes between the age of 15-29 is 8000, so these would be the annual number eligible. They reflect a high proportion of Maori and Pacific as per the numbers below However, I suspect that due to inadequate case-finding, the proportion actually prescribed these agents would be much lower than this number All those with longstanding T2D of young age of onset would already qualify under the microalbuminuria threshold.
All best wishes
Withh

Count of people in the Virtual Diabetes Register, by age-group and ethnicity, 2019

Age-group	Māori	Pacific people	Indian	European/ Other	Total
00-04	29	10	2	79	120
05-09	100	34	13	318	465
10 14	200	92	23	672	987
15-19	387	172	30	953	1,542
20-24	675	361	76	1,333	2,445
25-29	1,024	710	356	2,075	4,165
30-34	1,536	1,140	979	3,127	6,782
35-39	1,943	1,666	1,165	4,015	8,789
40-44	2,515	2,342	1,281	4,918	11,056
45-49	3,858	3,433	1,639	8,325	17,255
50-54	5,040	4,777	2,008	11,839	23,664
55 59	6,223	5,138	2,451	16,630	30,442

Count of people in the Virtual Diabetes Register, by age-group and ethnicity, 2019

Age-group	Māori	Pacific people	Indian	European/ Other	Total
60-64	6,063	4,812	2,650	19,705	33,230
65-69	5,324	4,351	2,435	21,823	33,933
70-74	3,873	3,237	1,861	23,580	32,551
75-79	2,412	2,122	1,252	19,466	25,252
80-84	1,383	1,075	686	14,307	17,451
85+	657	544	352	12,256	13,809
Total	**43,242**	**36,016**	**19,259**	**165,421**	**263,938**

From: Withheld under section 9(2)(g)(i)
Sent: Saturday, 17 October 2020 11:11 am
To: Elena Saunders <Withheld under section 9(2)(a)>; Diabetes Subcommittee <Withheld under section 9(2)(a)>
Cc: Peter Murray <Withheld under section 9(2)(a)>; Adam McRae <Withheld under section 9(2)(a)>
Subject: Re: PHARMAC additional request for advice regarding Special Authority criteria

Kia ora Elena

I have been looking at our young adult clinic figures at Withheld which show that during the 30 month period from May 2016 and October 2018 we saw a total of 171 adults of whom only 50 had type 2 diabetes. Worryingly, of those 50, only 35 young adults with type 2 diabetes (aged 16 15 years), were seen twice in that 30 month period. All had very poor glucose control as you can see from our attached unpublished report.

When compared to this total adolescent diabetes population in our catchment area, our clinic cohort captured 55% (75/136) of Europeans, 21% (45/218) of Pacific people and 12% (15/129) of Māori. These numbers suggest patients of non European ethnicities are under represented in our clinic (largely made up of T2D). Since our free adolescent clinics held at various locations in Withhel Withheld is so poorly accessed by young people with T2D, with all the effort our multidisciplinary team put into contacting them and providing support, they certainly aren't accessing this care through GPs.

As you can see from our attached report, the difference we make to young adults with diabetes in their glycemic control is very little Simple, effective treatment strategies such as SGLT2i and GLP1RA are urgently needed for youth, without them having to worry about hypoglycaemia, weight gain, capillary glucose monitoring, which our currently funded T2D medications produce SGLT2i and GLP1RA would make a real difference in these young adults with T2D and I would suggest a criterion that somehow makes these drugs to these individuals early, rather than waiting until they develop

microalbuminuria and other complications after they have already disengaged with health care services.

So what I would like to point out is that there are a much, much lower numbers of young adults with type 2 diabetes than these national VDR figures would suggest, that we actually have accessing diabetes care Whilst the younger bands below in the VDR are probably made up of approximately 50% with type 1 diabetes, the lack of seeing these young people with T2D in our free adolescent clinics is a concerning sign. Whilst I realise that age thresholds are a tricky one to include in any restricted access set of criteria, I do feel that the greatest benefit from these agents would be realised by being able to prescribe them in the relatively few people who have such early age of onset of type 2 diabetes, at whatever time they engage with either primary or secondary care

I hope that you can take this into consideration

Kind regards
Withh

Changes in the glycaemic control of 156 adolescents seen at a specialised diabetes clinic

For young patients with diabetes, the early and intensive control of hyperglycaemia can significantly delay the onset of vascular complications [1] However, avoiding such negative health outcomes requires sustained effort by both patient and clinician. Adolescents with diabetes present particular challenges in this regard and a therapeutic partnership is critical when navigating complex management issues [2] [3]. In recognition of this challenge, recent years have seen the evolution of specialised adolescent diabetes clinics [4]. Our established publicly-funded clinic is based in Withhe Withheld , the most ethnically and economically diverse urban region of New Zealand [5] Using a retrospective cohort study, we assessed the changes in glycaemic control for a cohort of patients seen in this clinic

We identified 171 adolescents (aged 16 25 years) seen in our clinic during the 30 month period from May 2016 to October 2018. This included all patients seen either for the first time or as follow up from a previous visit. For analysis, we excluded 15 patients who had only been seen once as of November 1 2018 One of those excluded had attended their first appointment but no subsequent appointments. The other 14 patients attended their first appointment but the study period ended before their second appointment was due This left 156 patients in the study cohort

Of the study cohort, 80 were male and 76 were female. 120 had type 1 diabetes, 35 had type 2 diabetes and one had monogenic diabetes. The median age was 16.7 years (inter quartile range 16.3 – 17.5 years). The median number of clinic encounters was 9 (IQR 6 - 15) over a median 930 days (IQR 454 – 1673 days) Europeans were the most prevalent ethnicity, accounting for 48% of the study population. Pacific people accounted for 29% of the total cohort, but made up almost 2/3 of those with type 2 diabetes (22/35) New Zealand Māori patients accounted for 10% of the total cohort, with an unexpected 87% (13/15) having type 1 diabetes.

We compared the study cohort to the total local population of adolescent patients with diabetes – all of whom are eligible to be seen in our clinic. Using laboratory data from 2018 we identified 548 adolescents in our catchment area with biochemical diabetes (fasting glucose >= 7 0 mmol/L or haemoglobin A1c (HbA1c) >= 50 mmol/mol on two separate occasions). When compared to this total adolescent diabetes population, our clinic cohort captured 55% (75/136) of Europeans, 21% (45/218) of Pacific people and 12% (15/129) of Māori. These numbers suggest patients of non European ethnicities are under-represented in our clinic.

After anonymising patient data, we compared two HbA1c values for each patient. The “baseline” value was the HbA1c recorded at the time of first ever clinic contact, whether that was during the study period or prior. The “last” value was the HbA1c at discharge from clinic, or November 1st 2018 for those not discharged. We analysed our patient group by gender, age at first clinic contact, diabetes type, ethnicity, number of clinic visits and baseline HbA1c. For “number of clinic visits” we divided patients based on their having more or less than the median of 10 visits. For “baseline HbA1c” we divided patients based on an HbA1c above or below 75mmol/mol (normal range < 48 mmol/mol). For each group, we assessed the net difference between the baseline and last HbA1c values. The metrics for comparison were the mean HbA1c and the proportion of HbA1c values that were under 65mmol/mol – the usual clinic cut off for maximum acceptable HbA1c. The results of these comparisons are displayed in table one.

For the group as a whole, the mean baseline and last HbA1c values were 86.9 mmol/mol and 85.2 mmol/mol respectively There were 46 patients with a baseline HbA1c < 65 mmol/mol and 38 patients with a last HbA1c < 65 mmol/mol. Neither of these reductions were statistically significant.

We identified three factors associated with a statistically significant change in diabetes control. The first of these was age greater than 16. Patients aged over 16 at referral had an improvement in mean HbA1c of 10.0 mmol/mol (p<0.02). Those aged under 16 showed a non-significant rise in mean HbA1c (2 2 mmol/mol, p=0 45) and a significant decline in the percentage with HbA1c < 65mmol/mol (10.4%, p<0.05). The second factor associated with significant improvement was higher baseline HbA1c. A baseline HbA1c > 75mmol/mol was associated with a 10.8mmol/mol improvement in mean HbA1c (p<0.001) and a 5.3% rise in the percentage achieving target HbA1c (p<0.01). Meanwhile, those with baseline HbA1c < 75 mmol/mol had worsening of both the mean HbA1c (+12 1 mmol/mol, p<0 001) and the proportions achieving target HbA1c (21 0%, p<0 01) The third factor associated with a significant change was Māori ethnicity. Māori patients experienced a 10 3 mmol/mol worsening of mean HbA1c (p<0 01) during the study period

An unanticipated outcome was a lack of association between HbA1c change and the number of clinic visits. Our study was not able to investigate how this observation relates to the efficacy of the adolescent clinic resources. Similarly, we could not assess how HbA1c results may have differed without clinic input We note that previous evaluations of adolescent diabetes clinics have found similar results to ours [3] [6] [7]. There were no differences in HbA1c change by gender or type of diabetes

We also note that within the nationalised New Zealand healthcare system the sodium glucose co-transporter 2 inhibitors (SGLT2i) and glucagon like peptide 1 receptor agonists (GLP1 RA) are not yet funded. These agents carry a low risk of hypoglycaemia and weight gain and convey renal and cardiovascular benefits Once these agents are available we anticipate high uptake and improved outcomes amongst adolescent patients with type 2 diabetes.

In summary, this study identified no significant change in hyperglycaemia for an adolescent cohort attending a specialised diabetes clinic. Additionally, we identified worsening control for those who entered the clinic at a younger age, had less severe hyperglycaemia at baseline or were of Māori ethnicity. At this point, we lack sufficient data to assess the contribution of our clinic to the glycaemic trajectory of these patients Similarly, it is not clear why those aged over 16 or with severe hyperglycaemia tended to improve with clinic input. Despite our focus on overcoming societal barriers to healthcare, we could not achieve equity in health outcomes for our high risk patients [4] [8] [9]. The apparent lack of engagement with those of Māori or Pacific ethnicity is an additional concern. Our data suggest that current best-practice adolescent clinic design may be inadequate for certain high-risk groups Improving health outcomes for our most vulnerable patients is a high priority that requires fit for purpose co designed services and active mitigation of barriers to healthcare.

References

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				Mean HbA1c (mmol/mol)				Percentage with HbA1c < 65mmol/mol			
	n (total)	% (male)	% (type 1)	Baseline HbA1c	Last HbA1c	Net change (95% CI)	p value	Baseline HbA1c	Last HbA1c	Net change (95% CI)	p value
Gender											
Male	80	-	*81*	89.1	83.9	-5.2 (-12.2 - +1.8)	0.15	28.8	28.8	0 (-14.0 - +14.0)	0.5
Female	76	-	*72*	84.6	86.5	+1.9 (-3.8 - +7.6)	0.54	30.2	19.7	-10.5 (-24.3 - +3.2)	0.07
Age at first contact											
</=16 years	106	*52*	*87*	83.7	85.9	+2.2 (-3.1 - +7.5)	0.45	33.0	22.6	-10.4 (-22.4 - +1.7)	**<0.05***
>16 years	50	*50*	*56*	93.6	83.6	-10.0 (-1.7 - -18.3)	**0.02***	22.0	28.0	+6.0 (-11.0 - +23.0)	0.76
Diabetes type											
Type 1 diabetes	120	*54*	-	86.9	84.1	-2.9 (-8.4 - +2.7)	0.31	29.2	23.3	-7.0 (-17.0 - +5.3)	0.15
Type 2 diabetes	35	*40*	-	87.8	89.8	+2.0 (-5.2 - +9.2)	0.66	28.6	25.7	-1.0 (-23.7 - +18.0)	0.39
Ethnicity											
European	75	*57*	*96*	81.3	79.3	-2.0 (-8.3 - +4.4)	0.57	34.7	29.3	-5.3 (-20.3 - +9.6)	0.24
Pacific Islander	45	*35*	*49*	99.4	96.6	-2.8 (-12.5 - +6.8)	0.48	17.8	15.6	-2.2 (-17.6 - +13.2)	0.39
Maori	15	*53*	*87*	86.2	96.5	+10.3 (-1 - +21.7)	**0.01***	6.7	6.7	0 (-17.9 - +17.9)	0.5
Indian	12	*50*	*58*	78.7	74.2	-4.5 (-18.5 - +9.5)	0.62	58.3	41.7	-16.7 (-56.7 - +23.3)	0.21
Other	9	*78*	*67*	83.2	72.6	-10.7 (-29.3 - +7.9)	0.41	44.4	33.3	-11.1 (-56.2 - +33.9)	0.31
Number of clinic visits											
>/=10	74	*50*	*88*	89.8	88.1	-1.7 (-9.3 - +5.9)	0.63	34.1	31.7	-2.4 (-16.8 - +11.9)	0.37
<10	82	*52*	*67*	84.3	82.5	-1.8 (-7.2 - +3.6)	0.58	23.6	16.7	-6.9 (-20.0 - +6.2)	0.15
Baseline HbA1c											
<75 mmol/mol	62	*50*	*79*	58.7	70.7	+12.1 (6.0 18.2)	**<0.001***	74.2	53.2	21.0 (37.8 4.0)	**<0.01***
>/=75 mmol/mol	94	*52*	*76*	105.4	94.7	10.8 (5.0 16.6)	**<0.001***	0	5.3	+5.3 (+0.7 9.9)	**0.01***

From: Withheld under section 9(2)(g)(i)
Sent: Sunday, 18 October 2020 7:43 am
To: Elena Saunders <Withheld under section 9(2)(a)>; Diabetes Subcommittee <Withheld under section 9(2)(a)>
Cc: Peter Murray <Withheld under section 9(2)(a)>; Adam McRae <Withheld under section 9(2)(a)>
Subject: Re: PHARMAC additional request for advice regarding Special Authority criteria

Further to my emails below, I wonder if the following tweak to the proposed criteria could be considered instead? I think this would be much clearer from a clinical perspective and would also result in relatively few additional people per year Given the figures for type 2 diabetes that I provided from our young adult diabetes clinic at Withheld, I would estimate this to be more realistically at around 400 additional cases treated per year Most of the historic cases of T2D diagnosed below the age of 25 would already qualify under the microalbuminuria text.

** if the patient was diagnosed below the age of 25, when the use of a 5 year cardiovascular risk is not appropriate, but the patient is thereby deemed at high lifetime risk of cardiovascular or renal complications, this cardiovascular risk assessment criterion can be completed based on the opinion of the treating clinician

Rather than

** If due to the patient's young age at diagnosis the use of a 5-year cardiovascular risk according to a validated risk calculator is not appropriate, but the patient is at a high lifetime risk of cardiovascular or renal complications, this cardiovascular risk assessment criterion can be completed based on the opinion of the treating clinician

It would have been good to discuss this with the rest of the subcommittee but I hope this information helps at such tight timelines.

Kind regards
Withh

From: Withheld under section 9(2)(g)(i)
Sent: Thursday, 15 October 2020 11:58 am
To: Elena Saunders <Withheld under section 9(2)(a)>
Subject: RE: PHARMAC additional request for advice regarding Special Authority criteria

Kia ora Elana

Comments below

I still feel uncomfortable about Pharmac funding medication and stating special authority criteria for an unlicensed indication

Wit

Questions to the Subcommittee:

1. **Are the proposed criteria above clear from a clinical perspective?** **Criteria 1-6 are clear, the highlighted section undermines all of the other criteria – what is young age at diagnosis ??**
2. **Considering the additional text highlighted in yellow, how many additional people per year do you consider would access these medicines compared to the counterfactual where this text was not added?** **Would need to ask paediatricians re their cohort, but I think you would have adult physicians arguing that all of their patients are now eligible for treatment on the basis of this**

PHARMAC
TE PĀTAKA WHAIORANGA

FILE NOTE

Subject:	Pan Pacific Nursing Association
Event Type:	Meeting
Author:	Sandy Bhawan
Attendees:	Pauline Fuimaono Sanders Manogi Eiao Alisa Olli Fakaola Otuasi Doana Fatuleai Hariet Pauga Safaato'a Fereti (To'a) President Sandy Bhawan & Scott Metcalfe – PHARMAC
Location:	ZOOM meeting
Date event took place:	19 October 2020 – 7pm 8pm

Meeting commenced via ZOOM at 7pm
Sandy Bhawan chaired

Welcome and introductions
Acknowledged the time taken to provide the feedback.
Offered the opportunity to provide any additional feedback.

Q & A recorded as follows:

- Withheld under : Is restriction solely to do with fiscal? Scott explained the fiscal reasoning
- Withheld under asked re: how we are affected internationally? Scott explained where we are at and that we want to review criteria & ensure those who need it get it
- Withheld under outlined the following: Pasifika people miss out on opportunities & don't speak up
- Asked what was the timeframe for prices to drop & so can get open listing for everyone, Scott explained in general terms

Scott explained the SA criteria consulted on

- Question was asked about access to these agents if a patient had 5 year CVD risk which was below 15% or if CVDRA was not appropriate because of age but he/she still had high HbA1c and risk of kidney disease could.
- Scott yes, covered in the footnote (as "If, due to the patient's young age at diagnosis, the use of a 5-year cardiovascular risk according to a validated risk calculator is not appropriate, but the patient is at a high lifetime risk of cardiovascular or renal complications, this cardiovascular risk assessment criterion can be completed based on the opinion of the treating clinician ")

Scott explained that any relevant practitioner can apply for SA and prescribe
Withheld under described their practice & not having to see endocrinologist a good thing lots of opportunity to get patients on it.

Withheld so far liking what I'm hearing

1. Wide range of prescribers ++
2. HbA1c >53, pretty good as most people way above 53!
3 Question if HbA1c is improved from 60+ to 53, will they still be eligible for the med? Answer: Yes, as approval valid without renewal
4. For Pacific & Māori absolutely important to include these criteria for eligibility to medicine.
5 Relationships very important eg; Pharmacists & Nurses if can Rx should be able to do so

With
There are many patients with an HbA1c >53, can we afford this, as it will be almost everyone!

Scott Yes, affordable Not expecting a budget blowout and expecting sector not to be prescribing this inappropriately. Mitigated by the 5-year CVDRA and refractory to 6/12 prior treatments limits.

Scott asked what their thoughts were on support required by sector

With we will need support to be educated + how to prescribe the meds.

Withheld Primary care colleagues want tools to improve outcomes. Excited that equity lens will be used.

Withheld – guidelines of treatment can be a barrier when you meet one criteria but not the other eg; HbA1c less than 53 but CVDRA really high, can these agents become first line agent for those with an independent high CVDRA Scott would look into this

Scott unfortunately, we are unable to list on 1 Dec because factoring in equity criteria. Scott asked in order to have Maori/Pacific ethnicity criteria built in how long would you be prepared to wait for?

Consensus: important to get this right for Pacific and Māori

Closing comments
Withheld Stay close so we can keep supporting you even at Board level.

Withh Thank you Sandy + Scott
Support feedback and general direction of PHARMAC's thinking
Thanks to the Pacific Nursing leaders and their voices here tonight

Withheld thanks, important for us to get this right.

Withheld – Pleased to get email from Elena and opportunity to have this audience. This is also the start for a new relationship with us

Withheld Mihi to Scott ++! Thank you for the talanoa and opportunity to input

Withheld – found this invaluable thank you. Pan Pacific Nursing Association will support PHARMAC for adding an ethnicity criterion and advocate for it.

Meeting ended 8pm

From: Withheld under section 9(2)(g)(i)
Sent: Monday, 19 October 2020 10:55 AM
To: Elena Saunders <Withheld under section 9(2)(a)>
Subject: Our hui

Nei raa ngaa mihi ki a koutou, Te Paataka Whaioranga

Thank you again for the opportunity to meet virtually and discuss our consultation feedback on the proposal to fund two new medicines for type 2 diabetes - both a SGLT2 inhibitor and a GLP-1 agonist.

We acknowledge your commentary that our written feedback has helped inform your thinking, that you found it 'valuable' but are challenged with fiscal resourcing. Additionally, we acknowledge your admission that internal processes and decision-making criteria application have not included engagement with Māori or with pro-equity expertise in the process. As discussed, we believe this has led to the development of special authority criteria that do not recognise the unjust distribution of the determinants of equity, nor the racialised system into which they will be placed. We are therefore challenged that you found our feedback valuable yet provide a draft of criteria that is fundamentally without change

We recognise your concerns are underpinned by political sensitivity and what you deem to be viewed as setting a 'precedent ' We assert you have previously set precedents by using alternate guises, e.g. indications. This is demonstrated in the funding of pembrolizumab for melanoma and not progressing funding immunotherapy (such as pembrolizumab) for non-small cell lung cancer (Pembrolizumab has therefore been funded in a piecemeal approach, without consideration for the equity implications as other indications became registered.)

If it is accepted that there cannot be removal of a special authority process, (which is your assertion not ours), then a targeted, genuine approach to pro-equity would include ethnicity as a special authority criterion on its own Any other option would, as explicitly stated by us, NOT be a pro-equity approach. This is a point of non-negotiation for us. We do not accept the continued state of privileging others whilst compounding the disadvantage for us as Treaty partners To be clear, it is not our preferred stance that there is a delay with this listing, as we have been waiting far too long. We are, however, unwilling to compromise on getting this 'right' and 'rite.' If more work is needed get this right, then this should be done, while acknowledging the role the process has had in any subsequent delay As further stated, we are available to assist in a resourced manner.

Our expectation is that PHARMAC will uphold the intent stated in its 'bold' goal of achieving medicines access equity by 2025. Further, there is authenticity in the sentiment presented in PHARMAC's Māori Strategy -Te Whai Oranga. This should be viewed as an opportunity for PHARMAC to deliver on its obligations as opposed to a conundrum in which to traverse Pharmac can no longer behave as a passive member of the system, and to achieve these goals, the inequity in the system must be acknowledged.

Our understanding is that you will be taking this feedback to the Board and seek legal advice We therefore request to be updated on your teams progress in this matter

We look forward to hearing back from you.

Withheld under section, on behalf of Te Roopuu Whakakaupapa Urutaa

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From: Elena Saunders
Sent: Monday, 19 October 2020 11:07 am
To: Withheld under section 9(2)(g)(i)
Cc: Peter Murray <Withheld under section 9(2)(a)>; Scott Metcalfe <Withheld under section 9(2)(a)>; Bill Kaua <Withheld under section>
Subject: RE: Our hui

Thanks With. We are working on a formal response to you, taking into account not only the written feedback, but also the additional insight from our hui. I hope this formal response will be with you in the next few days

Ngā mihi nui,

Elena

Elena Saunders (she/her) | Therapeutic Group Manager

PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
Cell: Withheld under | DDI: Withheld under | P: +64 4 460 4990 | www.pharmac.govt.nz

-------- Original message --------
From: Withheld under section 9(2)(g)(i)
Date: 19/10/20 6:07 PM (GMT+12:00)
To: Elena Saunders <Withheld under section 9(2)(a)>
Cc: Peter Murray <Withheld under section 9(2)(a)>, Scott Metcalfe <Withheld under section 9(2)(a)>, Bill Kaua <Withheld under section>
Subject: Re: Our hui

Ngaa mihi Elena. We look forward to hearing from you

With

From: bill.kaua <Withheld under section>
Sent: Tuesday, 20 October 2020 2:33 pm
To: Withheld under section 9(2)(g)(i); Elena Saunders <Withheld under section 9(2)(a)>
Cc: Peter Murray <Withheld under section 9(2)(a)>; Scott Metcalfe <Withheld under section 9(2)(a)>
Subject: Re: Our hui

Noted

Sent from my Samsung Galaxy smartphone.

From: Scott Metcalfe <Withheld under section 9(2)(a)>
Date: 23 October 2020 at 5:01:27 PM NZDT
To: Withheld under section 9(2)(g)(i)
Cc: Ken Clark <Withheld under section 9(2)(a)>, Peter Murray <Withheld under section 9(2)(a)>, Elena Saunders <Withheld under section 9(2)(a)>, Alison Hill <Withheld under section 9(2)(a)>, Bill Kaua <Withheld under section>
Subject: To Te Ropu Whakakaupapa Uruta PHARMAC response following hui on diabetes medicines

Kia ora With hold,

It was very nice meeting you and others on screen last Wednesday, and we really have appreciated the time you and others have taken to kōrero and provide responses to the diabetes medicines consultation.

Please find attached a letter to Te Rōpū Whakakaupapa Urutā from PHARMAC staff; would you be able to circulate this to the rest of the group, thanks?
It will be good to be working more on this together.

Ngā mihi
Scott

Dr R Scott Springford Metcalfe (was Scott Metcalfe) (he/him) | Chief Advisor Population Medicine / Deputy Medical Director; public health physician | MBChB DComH FAFPHM(RACP) FNZCPHM FNZMA

PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
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Please note I usually don't work on Wednesdays

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23 October 2020

Te Rōpū Whakakaupapa Urutā
www uruta maori nz

By email: Withheld under section 9(2)(a)

Tēnā koutou,

Treatments for type 2 diabetes

Ki a koutou ngā rangatira, tēnā koutou katoa

Thank you for the valuable feedback that Te Rōpū Whakakaupapa Urutā provided to Te Pātaka Whaioranga PHARMAC's recent consultation on the funding of new treatments for type 2 diabetes. We also appreciate the time members of Te Rōpū Whakakaupapa Urutā took to meet with us last week, to talk through your consultation response in more detail

Te Pātaka Whaioranga PHARMAC acknowledges the significant health inequities that exist in Aotearoa New Zealand These are unfair, unjust and unacceptable We recognise that Te Pātaka Whaioranga PHARMAC is a part of the system that has perpetuated these inequities, and that we need to both work ourselves and to exercise our influence and leadership within the sector to address these inequities

As noted in our discussion, given our budget position we are not currently able to fund these medicines for Type II diabetes without some funding criteria We took considerable external clinical advice in the development of the proposed Special Authority criteria to ensure they would target people who have the greatest health need using clinical criteria in line with our usual processes I note that an article on a recent audit of the proposed Special Authority criteria for these new treatments published in the New Zealand Medical Journal indicates that the proposed Special Authority criteria do target those patients with the worst diabetes outcomes in Aotearoa New Zealand, when compared with the 2018 ADA/EASD guidelines

However, we acknowledge that the proposed criteria do not specifically address the inequities and issues of the system these treatments would be funded within We agree that this an important opportunity to better a pro-equity approach to developing medicine access criteria, which could have far-reaching impact on our own work and that of other health sector agencies and funders. Your input to this so far has been very valuable, and we will want to continue our kōrero and joint mahi as we go forward.

You also suggested members with specific responsibility for equity be added to PTAC and other clinical advisory groups, and that Te Pātaka Whaioranga PHARMAC review its process for equity in funding decisions We are working to enhance our equity capabilities, including our processes related to funding decisions. We are actively working to improve the equity

capability of clinical advisory groups, including in the last recruitment round for PTAC But again, our mahi and approach to this is developing, and we are very open to further ideas and kōrero

We are very keen to progress with the funding of these treatments, but we also want to appropriately consider, and respond to, the concerns you and others have raised during consultation. We are currently formally working through all the consultation feedback and considering the range of issues and views raised We are mindful of the wero you and others have given us to get this right for Māori and for New Zealand, and again we appreciate the wider opportunities this affords.

We appreciate Te Rōpū Whakakaupapa Urutā offer to support us in developing our approach to equity, and we will be in touch again over the next couple of weeks to progress further discussions with you about this.

Again, thank you for your feedback and time, and it will be good to be working more on this together; kia mahi tahi tātou

Ngā manaakitanga,
Nāku noa, nā

Dr Scott Metcalfe (he/him) MBChB DComH FAFPHM(RACP) FNZCPHM FNZMA
Chief Advisor Population Medicine / Deputy Medical Director

From: Rachel Read
Sent: Wednesday, 4 November 2020 11:20 am
To: Amber Coyle <Withheld under section 9(2)(a)>; Hina Davis <Withheld under section 9(2)(a)>
Cc: Adam Bennet <Withheld under section 9(2)(a)>; Julian Robins <Withheld under section 9(2)(a)>; Richard Trow <Withheld under section 9(2)(a)>; Withheld under section 9(2)(a); Fiona Ryan <Withheld under section 9(2)(a)>; Lizzy Cohen <Withheld under section 9(2)(a)>; Jane Wright <Withheld under section 9(2)(a)>
Subject: Decision delayed for two new diabetes treatments

Kia ora Amber and Hina

This is a 'no surprises' update for Minister Hipkins and Minister Henare

On Thursday 5 November PHARMAC intends to notify stakeholders directly and through our website of a delay to making a decision on a proposal to fund two new diabetes treatments.

In September 2020 PHARMAC sought feedback on a proposal to fund two new medicines, under Special Authority, for type 2 diabetes through provisional agreements with two different suppliers

These medicines are a SGLT-2 inhibitor, empagliflozin, supplied by Boehringer Ingelheim as Jardiamet (with metformin) and Jardiance (without metformin), and a GLP 1 agonist, dulaglutide (Trulicity), supplied by Eli Lilly.

PHARMAC estimated that around 50,000 people in New Zealand would be eligible for treatment under the proposed Special Authority criteria for these medicines. The Special Authority criteria were specifically intended to enable access to these medicines for people who are at high risk of heart and kidney complications from type 2 diabetes. These are the people we understand to be at highest need, and also to have the greatest potential to benefit.

In its proposal to fund these medicines PHARMAC advised that if it was approved by the PHARMAC Board, funding for empagliflozin would commence on 1 December 2020, and dulaglutide would be funded as soon as practicable following Medsafe approval

While the feedback was overwhelmingly positive about the proposal to fund these two new medicines, some important questions have been raised that we want to consider further. PHARMAC is now carefully considering the feedback received and exploring a number of options for changes to the proposal to determine whether they would address the questions raised.

This means our decision on these medicines will be delayed, and these medicines will not be funded from 1 December 2020 as originally proposed. We are not currently able to provide a new timeframe for when a decision will be made

We understand that this delay is likely to be disappointing to many people. We will update stakeholders on our progress and timeframes as soon as we can.

If you require further information please let me know.

Regards Rachel

Rachel Read | Manager, Policy and Government Services | Engagement & Implementation

PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: Withheld under | P: +64 4 460 4990 | M: Withheld under section
www pharmac govt nz

From: CAC (Consumer Advisory Committee)
Sent: Thursday, 5 November 2020 3:12 pm
To: CAC Members <Withheld under section 9(2)(a)>
Subject: Diabetes paper for CAC meeting tomorrow CONFIDENTIAL

Kia ora koutou,

Attached is a paper for agenda item 5 of the CAC meeting tomorrow – Diabetes treatments RFP.

You will see that the paper captures a range of thinking from PHARMAC of our next steps in relation to this RFP A reminder that this, and all other papers provided to the committee, are confidential to you as a committee member. Much of the information in this paper has not been shared externally and we wanted to seek some early engagement with you as committee members in advance of our external engagement.

We're looking forward to having a kōrero with you about this during the meeting tomorrow

You may also be interested to read the article on Stuff that covers some stakeholder response to our update on the delay.

Note – a further email outlining the plans for the mihi whakatau/welcome tomorrow morning will be coming to you this afternoon as well.

Ngā mihi,

Janet

COMMERCIAL IN CONFIDENCE

PHARMAC
TE PĀTAKA WHAIORANGA

MEMORANDUM FOR CONSUMER ADVISORY COMMITTEE MEETING 6 NOVEMBER 2020

To:	Consumer Advisory Committee members
From:	Elena Saunders, Therapeutic Group Manager; Janet Mackay, Manager, Implementation Programmes
Date:	November 2020

Type 2 diabetes treatments RFP

Purpose

The purpose of this paper is to provide the CAC with more detail of PHARMAC's thinking about next steps for a proposal for the funding of two new type 2 diabetes treatments, and background for further discussion in relation to implementation of eventual decisions. The paper also provides an example of the thinking and analysis that PHARMAC staff undertake to respond to various types of feedback.

Recent consultation on proposal to fund treatments

PHARMAC recently publicly consulted on a proposal to fund two new treatments for type 2 diabetes. Consultation closed on 2 October and we received a rich and varied range of consultation feedback Most of the feedback we received was strongly supportive of the funding of these two treatments. However, some issues raised in consultation need more time for full consideration. This means we are not able to progress with the proposal in the timeframe we had originally proposed

The original proposal was to fund an SGLT 2 inhibitor (empagliflozin and empagliflozin with metformin) from 1 December 2020, and a GLP 1 agonist (dulaglutide) from date of Medsafe approval (which we anticipate would be at some point in 2021).

What is PHARMAC doing now?

Working through feedback

PHARMAC staff have been working through the consultation responses and considering how we could amend the proposal to respond to the issues raised in consultation. Some particularly complex issues raised in consultation that we are working through include:

- Concern that the proposed Special Authority criteria would mean some Māori and Pacific people would miss out on getting access to these treatments, and that this would increase existing inequity in access to medicines and health outcomes
- Concern that equity expertise had not been sought or integrated into the assessment of these treatments for funding

- A request for the inclusion of an ethnicity criterion as part of the Special Authority criteria
- Concern that funding these medicines provides an opportunity to address health inequities through a different approach, and that this opportunity may be lost if the proposal (as it was consulted on) progressed.

Since the formation of our Medicines Access Equity programme of work in late 2017, we have been considering how we can improve our processes to ensure we are focussed on equity. In developing the proposed Special Authority criteria for the diabetes treatments, we gave serious attention and sought extensive and specific clinical advice, on equity considerations. We were satisfied that the proposed Special Authority criteria would capture those people who were most likely to benefit (including a significant number of Māori and Pacific people, who carry the highest burden of type 2 diabetes in Aotearoa New Zealand) This approach has been confirmed with an audit that was published recently in the New Zealand Medical Journal. However, some consultation responses considered we needed to go further to ensure equitable access was achieved.

Some respondents to consultation noted that the healthcare system itself perpetuates inequities for Māori and Pacific people. It was considered by some that PHARMAC's proposed Special Authority criteria would unintentionally exclude some people who, on the basis of unequal access to healthcare, would benefit from treatment and therefore perpetuate system inequities.

These are important considerations, and we want to consider all the options we have in front of us in relation to this proposal. This means that the proposal will not progress as quickly as we had originally indicated.

PHARMAC is very keen to progress with funding these treatments for type 2 diabetes, but our budgetary management position means we are not currently able to do that without some funding criteria In fact, some consultation feedback suggested that funding of these treatments without criteria/ restrictions would be a 'passive' approach that would not proactively address equity challenges PHARMAC is not able to 'open list' (i e fund without any Special Authority criteria/funding restrictions) both the two treatment options, i e a SGLT 2i and a GLP 1 agonist.

Considering options

The options below set out our early thinking about some of the different options for our next steps for the diabetes proposal, considering the feedback we received in consultation. While some of these options are not likely to eventuate (eg, not progressing with the funding of at least one of these medicines), they are included to show a diverse range of options that we consider are open to us right now.

During the meeting with the CAC we will discuss some of the different factors we are considering for each option, including the trade offs, such as timeframes & resource required, ability to meaningfully improve access equity, and our Factors for Consideration.

- Progress with current proposal unchanged, no further amendment to Special Authority

- Progress with current proposal unchanged, no further amendment to Special Authority, but much stronger cross sector monitoring and implementation approach

- Progress current proposal with inclusion of an ethnicity criterion in the Special Authority

- Progress current proposal and consider the option of inclusion of an ethnicity criterion in the Special Authority at a later point

- Significantly alter the proposed Special Authority criteria, without including a specific equity criterion

- Decline the current proposal and do nothing (ie stop progression)

We wanted to share this to give CAC members an insight into the types of things we consider and weigh up when making funding decisions, and to provide background for further discussion once an approach is settled on and the decision is made

CAC input will be sought into implementation

We plan to engage with the CAC more closely about the implementation of the decision, and activities that PHARMAC can consider to support uptake of these treatments, when we are a little closer to the decision making for this proposal.

While we have no specific questions to bring to the CAC about this current process, there will be an opportunity during this November CAC meeting to discuss our approach and answer any questions.

From: Withheld under section 9(2)(g)(i)
Sent: Thursday, 12 November 2020 2:56 pm
To: Scott Metcalfe <Withheld under section 9(2)(a)>
Cc: Elena Saunders <Withheld under section 9(2)(a)>; Trevor Simpson <Withheld under section 9(2)(a)>; Bill Kaua <Withheld under section>
Subject:

Tena koe Scott.

Nei raa ngaa mihi o te raa ki a koe.

Thank you for your recently letter following our October meeting. Please find attached a letter from Te Rōpū Whakakaupapa Urutā

We look forward to the ongoing communication between our groups.

Ngā mihi, nā
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Withheld under section 9(2)(g)(i)
Withheld
Withheld under section 9(2)(g)(i)

Te Rōpū Whakakaupapa Urutā
NATIONAL MĀORI PANDEMIC GROUP

Dr Scott Metcalfe
Chief Advisor Population Medicine
PHARMAC
Emailed to: Withheld under section 9(2)(a)

Cc: Elena Saunders (PHARMAC Therapeutic Group Manager) - Withheld under section 9(2)(a)
Trevor Simpson (PHARMAC Chief Advisor, Māori) - Withheld under section 9(2)(a)
Mr Bill Kaua (PHARMAC kaumatua) - Withheld under section

Tēnā koe Scott mā,

Re: Proposal to fund two new medicines for type 2 diabetes - empagliflozin and dulaglutide

He kawau ka tuku ki roto i te aro maunga

Thank you for your letter dated 23 October 2020 following our zoom meeting to discuss the decision to fund empagliflozin and dulaglutide. In this discussion we outlined the equity risks we had identified in the original PHARMAC proposal. We are pleased to see that this discussion resonated with the team and has led to deeper consideration on access to these medications. Your letter to us acknowledges our three key concerns that the funding proposal failed to acknowldge a) the well-documented inequity in healthcare access and delivery in Aoteora, b) the increased need of Māori and Pacific individuals living with diabetes and c) the role that PHARMAC has in being an active, pro-equity contributor to healthcare delivery. We are pleased to see PHARMAC consider it's location within an inequitable system, and look towards a more active role in achieving equity.

We maintain our stance, that a pro-equity approach to the funding of empagliflozin and dulaglutide is required, and would be achieved with either the removal of a special authority, or the introduction of a equity (Māori and Pacific Island) criterion.

We are aware of PHARMAC's decision not to progress the 1st December release of these medications and their proposed funding. We are cautiously hopeful that this is an indication of a commitment of the PHARMAC team to meaningfully engage with a pro-equity approach. We are, however, deeply concerned that a right delayed is a right denied, and while we support PHARMAC getting to the right decision, we equally strongly advocate for rapid and decisive action. It can not be ignored, that any unnecessary delay, on top of the 10 years we have already been waiting, will result in forgone health benefit.

Te Rōpū Whakakaupapa Urutā recognises the recent appointment of Trevor Simpson as Chief Advisor, Māori within PHARMAC. This is seen as a positive move towards equity within the PHARMAC processes. However, we are concerned that in the recent statement of performance expectation published by PHARMAC, there was no mention of the equity 'bold goal' and the 2025 date no longer appears anywhere in the document. We strongly hope that this is not an indication of PHARMAC relinquishing its desire to 'eliminate inequities in access to medicines by 2025'.

Te Rōpū Whakakaupapa Urutā is open to remaining engaged in this conversation with PHARMAC and available to further discuss how that engagement might look. We will continue to monitor very closely how PHARMAC choses to progress this extremely important decision.

Nāku noa, nā

Withheld under
Withheld under section 9(2)(g)

Te Rōpū Whakakaupapa Urutā

From: Elena Saunders <Withheld under section 9(2)(a)>
Sent: Friday, 20 November 2020 1:17 PM
To: Withheld under section 9(2)(g)(i); Withheld under section ; Withheld under section 9(2)(g)(i)
Cc: Geraldine MacGibbon <Withheld under section 9(2)(a)>; Trevor Simpson <Withheld under section 9(2)(a)>; Scott Metcalfe <Withheld under section 9(2)(a)>
Subject: Summary of our kōrerorero today

Tēnā koutou,

Thank you again for your time this morning – I personally am really valuing our ongoing kōrerorero, and it is so helpful in shaping our thinking.

My overall summary of our discussion is as follows;

We discussed one of the options that could be used to include ethnicity within a broader Special Authority criteria (see example wording below)

- Urutā attendees acknowledged that this was an incremental change compared to previous iterations
- Urutā attendees reiterated the position that this would not be sufficient to address the feedback already provided, and were disappointed not to see a broader criterion addressing ethnicity
- Urutā attendees provided some specific feedback on wording that should be considered (incorporated into example wording below)
- Urutā attendees reiterated a preference for SA criteria that enabled access to all Māori or Pacific people with type 2 diabetes regardless of other clinical features. Noted this would include no HbA1c requirement, no requirement to have trialled metformin or for use in combination with metformin (acknowledging the prior correspondence had included an HbA1c cut-off).

- We briefly discussed ongoing partnership
  - ES noted that we welcome this engagement and would like to continue in a more formalised fashion – we are working on how this might look
  - With noted that it would be critical to partner with Māori on the development and implementation of any monitoring activities
  - Urutā attendees expressed a degree of cynicism that ongoing partnership and progress would actually be made

Example wording: "Patient has a high lifetime cardiovascular or renal risk associated with their Māori or Pacific ethnicity"

I trust this captures the key points (albeit at a high level). If you think I've missed anything please let me know – and I look forward to receiving feedback prior to Monday if that is achievable.

Ngā mihi nui,

Elena

Elena Saunders (she/her) | Therapeutic Group Manager

PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
Cell: Withheld under | DDI: Withheld under | P: +64 4 460 4990 | www.pharmac.govt.nz

From: Withheld under section 9(2)(g)(i)
Sent: Friday, 20 November 2020 1:27 pm
To: Elena Saunders <Withheld under section 9(2)(a)>; Withheld under
Withheld under section 9(2)(g)(i); Withheld under section
Cc: Geraldine MacGibbon <Withheld under section 9(2)(a)>; Trevor Simpson
<Withheld under section 9(2)(a)>; Scott Metcalfe <Withheld under section 9(2)(a)>
Subject: RE: Summary of our kōrerorero today

Thanks Elena

I've just been tracking some of the conversations amongst Uruta members. To be direct and clear – the associated with Maori or Pacific ethnicity' is also getting a beating – deficit framing etc. "Patient has a high lifetime cardiovascular or renal risk associated with their Māori or Pacific ethnicity" is going to be contested strongly

Ngā mihi

Withheld under section 9(2)(g)(i)

Withheld under section 9(2)(g)(i)
W

-----Original Message-----
From: Withheld under section 9(2)(g)(i)
Sent: Friday, 18 September 2020 11:56 a.m.
To:

Morena

Thanks to all those people who have commented either as reply all or directly to me. With this feedback I have revised the draft, specifically including Withheld under section 9(2)(a) points against SA under "what will help people with diabetes and their whanau accessing these medications", and Withheld points around implementation under "tools or approaches to support prescribers" I acknowledge the linguistic guidance from Withheld under on the plural, "and/or" wording of criteria 2 which would otherwise create confusion

I have also added a piece on youth with T2D who would benefit from earlier (open access) use of these medications before waiting for microalbuminuria to develop, however, I very much doubt that feedback on open access will affect this process. The reality is very much that SA (at least initially) will be required for these medications, and if we can impact on minor tweaks to the criteria at this stage, this will be the most useful feedback.

While I understand it is not possible to achieve a consensus feedback, I think it is important to provide as much discussed and considered feedback as possible. I have found the comments in this email trail extremely helpful in compiling this response. I hope that some of you who would not have provided feedback have decided to do so in light of the discussions below and/or (+/- !) would like to add your name to this one

Please let me know if you would like to be named on the attached version or any minor edits before next Friday 25 September.

I am planning to convene a meeting with Pharmac and a multispecialist group in Auckland on Wed 18th November to discuss effective implementation of these new medications as I understand funding arrangements will be finalised by this date The focus for this meeting will be how to implement the proposed SA criteria for maximum patient benefits. Please let With know if you can make this date and she will be following up with you around travel arrangements and agenda closer to the time.

Nga mihi

Withh

Good afternoon all,

Following on from Withh's email below, this is a meeting request for the Pharmac/specialist meeting on the 18th of November We have reserved a room in the University of Auckland Grafton Campus If you are able to attend, we appreciate if you could please accept the request as soon as possible. The agenda is being finalised and will be circulated over the next few weeks

The Maurice Wilkins Centre does have limited funding available to support travel- for those of your outside of Auckland please contact Withheld under section 9(2)(g)(i) if you would like travel arranged. We will ensure a zoom link is available for those who have other commitments and are unable to attend in person

Lunch will be catered from 12 1pm, so if you have any dietary requirements please also send these through.

Many thanks
Withheld under section 9(2)(g)(i)
Maurice Wilkins Centre
https://smex12 5 en ctp.trendmicro.com:443/wis/clicktime/v1/query?url=http%3a%2f%2fwww.mauricewilkinscentre.org&umid=90d445dc-6b31-4103-8f1c-f963f919dbf8&auth=bb7c7bbf7acee6ae97e29073e34f3e8b1808c238-203349f5be9529d25ee8bbfe0f08948624039d49
Withheld under

Kia ora koutou

As we await the decisions around SGLT2i/GLP1RA funding for people with Type 2 diabetes, which should be announced prior to our meeting, please find an agenda below for our meeting on 18th November. In light of these paradigm-shifting new drugs for T2D, CVD and CKD being funded, I think it would be of value to discuss tangible ideas/methods/evaluations to drive rapid and equitable prescribing of these medications.

Lunch 12 1pm, Session 1: 1 2.30pm
Tea break 2 30 3pm, Session 2: 3-4 30pm
Meeting close 4.30pm

Titles are currently placeholders only (lack of imagination here is mine) Speakers are indicative of those who have kindly agreed to leading the discussion in this area from their specialty (or that I have seen that you are coming and volunteered you to do so!) Most valuable time is to allow discussion around these topics, so everyone can share their ideas from their networks and places of work relating to care of T2D patients that can be used for most benefit

Looking forward to seeing all of you who can make it via zoom or in person
Nga mihi
Withh

From: [redacted] on behalf of Maurice Wilkins Centre <maurice-wilkins-centre@auckland.ac.nz>
Date: Tuesday, 17 November 2020 at 4:24 PM
Subject: Combined specialist meeting

17th November: Updated programme for meeting tomorrow is attached. Zoom link and map for meeting room are included in the programme.

Dear all,

Please see the email from [redacted] below regarding the upcoming meeting on the 18th of November This has also been separately via email.

Just a reminder to those who have not yet done so, to please indicate your availability for this meeting by either accepting or declining this meeting request. The MWC does have a small amount of funding available to assist with travel If you would like travel booked, please contact [redacted] (Ccd) by the 6th of November. For those who are Auckland based and intend on joining via zoom, we would also appreciate you letting [redacted] know (for catering purposes)

Best regards,
MWC admin

From: [redacted]
Sent: Monday, 23 November 2020 12:36 p.m.
To: [redacted]

Withheld under section 9(2)(g)(i)
Withheld under section 9(2)(g)(i)
Withheld under section 9(2)(g)(i)
Withheld under section 9(2)(g)(i)

Subject: Re: Combined specialist meeting summary draft 1 to Pharmac with appendices A D included

Apologies for the multiple emails, and for missing out some people who attended or sent apologies – I have now added Withheld and Withheld to this list and put together the Appendices A-D so please also have a look at these and let me know of any corrections. I will finalise Appendix C as I hear back from you and hope to finalise the draft summary of discussions by the end of this week.
Thank you
[redacted]

Subject: Re: Combined specialist meeting summary draft 1 to Pharmac

Kia ora koutou

I would like to thank everyone who attended the meeting on the 18th of November either in person or via zoom. I realise many of you could not attend and sent your apologies. It was a very important discussion and one that we have been asked to provide a meeting summary back to Pharmac, after reflecting on these discussions with the wisdom of a wider and diverse group of specialists.

Several of you have already responded to me with key points especially around the inclusion of the ethnicity wording for restricted access criteria for SGLT2i/GLP1RA. Given Pharmac have specifically asked for clinical justification for the ethnicity wording in the restricted access criteria and potential risks, I have tried to include these in the attached meeting discussion summary as succinctly as possible

I am happy to receive comments from each of you. Please keep the subject heading so I can more easily track all comments as reply all or reply to me, by "conversation".

In interests of providing a timely response, I hope you can provide any feedback by Thursday 26th November.

Thank you

Nga mihi

[redacted]

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Withheld under section 9(2)(a)

From: Withheld under section 9(2)(g)(i)
Sent: 24 November 2020 10:21
To: Withheld under section 9(2)(g)(i)
Withheld under section 9(2)(g)(i)
Withheld under section 9(2)(g)(i)
Withheld under section 9(2)(g)(i)
Withheld under section 9(2)(g)(i)
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Withheld under section 9(2)(g)(i)
Subject: RE: Combined specialist meeting summary draft 1 to Pharmac with appendices A-D included

Kia ora koutou,

I have an alternative proposed SA criteria highlighted in yellow

1. Patient has type 2 diabetes; and patient with HbA1c >75mmol/mol despite maximum tolerated doses of oral antidiabetic agent(s) for 6 months, OR 2-6 apply
2. Patient has not achieved target HbA1c (of less than or equal to 53 mmol/mol) despite maximum tolerated doses of oral antidiabetic agent(s) and/or insulin for at least 6 months; and
3 Treatment is to be used in conjunction with other measures to reduce cardiovascular risk in line with current standard of care; and
4. Treatment will not be used in combination with a funded GLP-1 agonist; and
5 Treatment must be used as an adjunct to oral antidiabetic therapy and/or insulin; and
6. Any of the following:
    1 Patient has pre existing cardiovascular disease or risk equivalent*; or
    2. Patient has a 5 year absolute cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator; or
    3. Patient has diabetic kidney disease**

Thank you for all valuable comments from everyone, and my summary reasoning is as follows: essentially this may be a clinical criteria that has more equity focus than the original Pharmac proposed criteria by increasing eligibility and uptake of Maori and Pacific people and may get the new meds funded in a timely matter at least for the higher priority groups initially.

I agree with With that the ideal option is universal access, but Pharmac has indicated this is not affordable at this point in time, and history tells us we will get universal access eventually (like statins in the past), and getting timely access right now for high priority groups who benefit the most would be important albeit with SA is a compromised option.

Trying to get an ethnic based SA access criteria across the line as we are proposing in the meeting will be subjected to substantial delays in access of the new meds for all for a range of reasons including human rights, legal issues as Withh helpfully summarised, and the delay of access of any kind will widen inequity. Indeed, this may well be one of the key reasons why there is a delay in funding the new meds.

Addressing the wider system issues are arguably more important on equity than fighting the battle on ethnic based SA criteria. Indeed, resources to enable proactive and opportunistic care that delivers the comprehensive package of care to manage metabolic risk factors are more important. Ethnic or SES based interventions may be more effective elsewhere, e g primary health care funding. It is important to fight the battle that perhaps matters the most.

We also have to clinically justify the proposed ethnic based SA criteria given that there is limited data on CVD outcomes on people with diabetes without overt cardiovascular or renal disease, long term safety profile of glycosuria is lacking, the new agents have modest improvement in glycaemia (and CVD benefits) compared to other agents. Therefore, these new agents are "in additional to" but "instead of" first line agents We also need to anticipate any evidence based counter arguments For example, as per our current previous proposal with the ethnic criteria, we will need to justify why some population subgroups with diet control diabetes with a HbA1c of 54 on the basis of ethnicity alone will be prioritised to have new meds ahead of people with no diabetes but have HFeEF or macro-albuminuria where there is RCT trial evidence of hard outcome benefits in hard cvd and renal outcomes There are potential harms in advertently widening inequalities in other areas with significant health need beyond ethnic equity as we know there are multiple dimensions of equity.

Therefore, we need to be more active in addressing the wider equity issues across the system, that includes cost of care, model of care (e g how to we turn a passive system into an proactive and opportunistic one more universally). I know there are some GP practices that do better than others in that regard.

The need for combined guidelines that support people's journey and care pathways. E.g. if statins are perhaps twice is effective and clinical benefits are much more established than the new agents we are proposing, how come we are not lowering the active recommendation threshold as per international guidelines to consolidate better primary prevention of CVD? We also need to improve access to the whole of system information at the point of care.

The reality is that the uptake of the new medicine will take time, therefore getting past the line using a clinical proxy like an additional HbA1c criteria without other indications, to get pass the line is important Using a HbA1c threshold at 75, and will increase uptake by up to 8% of people with diabetes, of which majority will be Maori and Pacific people in the Withheld under .

There is much work to do to ensure safe and effective implementation of the new medicines, given the new agents are less effective than current first line agents and safety profile is less known and many safety protocols of the trials need to replicated in some way in the real world (frequent foot checks to avoid amputation), We need to deliver a packaged care to optimise are in relation to renal/DM/CVD risk, and using the availability of meds to renew focus and motivate providers to review people with diabetes and amenable risk factors more actively. For most cases, the initial action from the packaged care is not necessarily about starting the new meds, but actively addressing amenable risk factors, and CVD and renal risk. However, there is no doubt having the new meds available as indicated is helpful as part of the package.

Finally, I agree with many equity advocates that we should be aiming for the best health outcomes possible for everyone in NZ, which is better than the current healthy life expectancy or health outcomes of the any population groups internationally.

Kind regards,

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From: Withheld under section 9(2)(g)(i)
Sent: Tuesday, 24 November 2020 10:30 am
To: Peter Murray <Withheld under section 9(2)(a)>
Subject: FW: Combined specialist meeting summary draft 1 to Pharmac with appendices A-D included

Hi Peter,

This is my reply to Withh's request. FYI.. This is my suggestion, and Withheld under also thinks that ethnic based criteria should not sit in the SA for the new diabetes meds, as there are a number of inadvertent issues, but may better suited elsewhere.

The reality is that adding the sole HbA1c >75 mmol/mol may not increase potential uptake and overall budget by too much, may be around 5% nationally? (I do not have CVD risk in my data, and Auckland had proportionally more Maori and Pacific people), and uptake is not always immediate.

The priority is perhaps get the new meds past the line, the use that as a motivating factors, for provide to review all patients with diabetes, (optimise first line treatment, recall people with persistent hyperglycaemia, optimise CVD risk management, etc).

Happy to chat through if that helps.

Kind regards,

Withheld under section

From: Withheld under section 9(2)(g)(i)
Sent: Tuesday, 24 November 2020 4:18 PM
To: Withheld under section 9(2)(g)(i)
Subject: FW: Combined specialist meeting summary draft 1 to Pharmac with appendices A D included

Hi With

I have forward my comments to Peter Murray at Pharmac in regard to new diabetes meds. Just double checking as we discussed yesterday that you are happy for me to say that the ethnic based criteria should lie with other interventions (e.g. primary care funding) rather than having as a separate ethnicity criteria as part of speciality authority for the new diabetes meds.

Checking if you are ok with my suggestions below, and please feel free comment or amend as appropriate, as Peter Murray was asking about your views as well, as he rang me this pm.

I understand from Peter there are 2 camps here: one is to have access as soon as possible, and the other is to get the SA criteria right first.

My view is to get access to the highest priority group ASAP, even if we ended up using Pharmac original more restrictive criteria which is reasonably aligned with evidence. Apparently any change in criteria would result in further delay in access.

History tell us that the SA criteria may change over time, with new evidence and when prices of medicine goes down. (and we still need to do all about those things I talked about below).

Your thoughts, (just doubling checking if you are happy for me to forward your comments to Pharmac)

Kind regards,

Withheld under

From: Withheld under section 9(2)
Sent: Tuesday, 24 November 2020 6:13 p.m.
To: Withheld under section 9(2)(g)(i)
Subject: RE: Combined specialist meeting summary draft 1 to Pharmac with appendices A D included

Thanks Withh, your approach sounds very sensible. I would not be supportive of ethnic-based criteria for medications unless there was evidence that the utility/effectiveness of the medication varied by genetic type. Some medications do show that proclivity, but these ones (AFAIK) do not. By selecting good criteria you are capturing those most at risk – including M & P – as you note And targeting can be added at the primary care funding level, particularly around better integrated weight management approaches for our >75mmol/l people with diabetes – getting these medications into the mix will be very helpful.

Withh

Withheld under
Withheld under section 9(2)(g)(i)
Withheld under section 9(2)(g)(i)

From: Withheld under section 9(2)(g)(i)
Sent: Tuesday, 24 November 2020 8:58 am
To: Elena Saunders <Withheld under section 9(2)(a)>
Cc: Scott Metcalfe <Withheld under section 9(2)(a)>; Trevor Simpson <Withheld under section 9(2)(a)>; Bill Kaua <Withheld under section>
Subject:

Teenaa koe Elena

Thank you for our meeting on Friday. Please find attached a summary of our thoughts following that discussion We will, of course, continue to be interested in the progress of this kaupapa with SLT

Ngā mihi, nā
Withheld under section 9(2)(g)(i)
Withheld under section 9(2)
Te Rōpū Whakakaupapa Urutā

Te Rōpū Whakakaupapa Urutā
NATIONAL MĀORI PANDEMIC GROUP

Elena Saunders
Therapeutic Group Manager
PHARMAC
Emailed to: Withheld under section 9(2)(a)

Cc: Dr Scott Metcalfe (Chief Advisor Population Medicine) - Withheld under section 9(2)(a)
Trevor Simpson (PHARMAC Chief Advisor, Māori) Withheld under section 9(2)(a)
Mr Bill Kaua (PHARMAC kaumatua) - Withheld under section 9(2)(a)

24 November 2020

Tēnā koe Elena mā,

Re: Proposal to fund two new medicines for type 2 diabetes - empagliflozin and dulaglutide

He kawau ka tuku ki roto i te aro maunga

Thank you for updating us on your progress over zoom on 19th November. We acknowledge that you have been working on progressing a pro-equity approach to the special authority for these medications. We maintain our stance, that a pro-equity approach to the funding of empagliflozin and dulaglutide is required, and would be achieved with either the removal of a special authority, or the introduction of an equity (Māori and Pacific Island) criterion. We have proposed a criterion that is added to the already proposed criteria that states

"OR
Patient is of Māori and/or a Pacific ethnicity and has an HbA1c above 53mmol/mol"

We understand that you have received legal advice that this would require an additional consultation period, which would delay the release of these medications. We refute this. Equity or ethnicity criteria are already available in clinical medicine, as are demographic criterion (i e deprivation criteria on oral contraceptive pill). And this decision has been well responded to in consultation already. In our opinion, the decision to introduce a pro-equity criterion already complies with government policy and the New Zealand Public Health and Disability Act 2000, on whose behalf PHARMAC act. In addition, we believe that Aotearoa New Zealand is ready for a bold and brave stance from PHARMAC and that any negative feedback, which we believe will be small, will occur equally with a more 'palatable' option (such as below).

In the meeting you presented an alternative option for an criterion. In the first alternative option presented to us in that meeting we noted significant concerns including:

- while this option is a progressive step compared with earlier iterations, it is still disappointingly short of a true pro equity approach
- the deficit framing language that placed the cause of the increased cardiovascular or renal risk inherently with Māori and/or Pacific individuals and neglects the sociohistorical colonial context of such differentials of outcome

- the reliance on the clinician to measure clinical need, even though there is well documented undertreating of Māori and Pacific individuals in healthcare services
- the absence of renal disease risk, of which Māori and Pacific individuals living with diabetes carry the most increased risk

While we would like it to be very clear that we believe this is a inferior option, we have adjusted the wording of the criterion presented to somewhat reduce the concerns above.

"OR

The patient has a high lifetime cardiovascular or renal risk AND is of Māori and/or a Pacific ethnicity"

Lastly, we call on PHARMAC to be brave, to be bold, and to make a timely, yet fair decision. Te Rōpū Whakakaupapa Urutā is open to remaining engaged in this conversation with PHARMAC

Nāku noa, nā

Withheld under
Withheld under section 9(2)(g)(i)

Te Rōpū Whakakaupapa Urutā

From: Withheld under section 9(2)(a)
Sent: Wednesday, 25 November 2020 3:33 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: Feedback re Proposal to fund two new medicines for type 2 diabetes

Pharmac Consultation Committee
PHARMAC
PO Box 10254
The Terrace
Wellington 6143
consult@pharmac.govt.nz

Dear Pharmac Consultation Committee,

Te Akoranga a Māui are an indigenous group within the Royal New Zealand College of General Practitioners, who represent over 200 Māori general practitioners. While we welcome the news to include the medications, empagliflozin and dulaglutide, as funded treatment options for type 2 diabetes in Aotearoa, we believe this has to be done with careful consideration to ensure access to these medications is equitable. We understand that PHARMAC has proposed utilising Special Authority (SA) criteria in order to restrict access to these medications This is of concern to us because using SA criteria, could inadvertently limit access to Māori and Pacific populations despite being most likely to benefit from these medications

The SA criteria that is proposed for these medications relate to a number of documented failings of the health system. The 2018/19 New Zealand Health Survey has shown 41% of Māori and 36% Pacific report unmet need in primary health care in the past 12 months. Evidence shows that Māori are prescribed oral hypoglycaemic medication or started on insulin therapy at lower rates than non Māori and are less likely to have annual diabetic screening, frequent HbA1c measurement, annual albumin creatinine ratio measurement or a cardiovascular risk assessment. Therefore, many Māori are unlikely to meet the SA criteria for these medications due to issues with access NOT due to their health need This inequity in access should be well known to PHARMAC as your CEO, Sarah Fitt, recently presented on this issue Sarah reflected specifically on the inequity of access to medication and ongoing monitoring of chronic conditions and provided evidence about Māori receiving fewer prescriptions noting 50% less scripts are provided to Māori compared to non Māori for CVD risk and the inappropriate prescribing of NSAIDs.

We are also concerned about SA criteria that only subsidises one of the medications in a population who are likely to have benefit from both due to increased risk of complications such as renal failure and heart disease. We know that our Māori population is more likely, 7 times more likely, to develop end-stage renal disease compared to other New Zealanders. It is very unlikely that the "other" medication could be self-funded in this population group

If you were still to consider a SA then we believe it must include a waiver of criteria for Māori and Pacific patients, for example the necessity of maximising of other medications first or requirements of diabetic complications monitoring. This relates to our point above as those who have better access to primary care, medication and monitoring will be able to access these medications at greater rates, rather than those who will benefit the most from them.

Monitoring of medication access with an equity lens is required but we suggest that interventions for equity need to occur prior to the populations access to medication. By working with

organisations such as Te Rōpū Whakakaupapa Urutā, Te ORA or our organisation early and collaboratively a relationship and partnership can be developed

In conclusion Te Akoranga a Māui are very happy that these drugs will soon be available for our patients but we believe what PHARMAC has presented did not consider the patients who need them the most and we have a real concern our Māori (and Pacific) population will be disadvantaged once again.

If PHARMAC is truly considering how to respond to funding these medications in a pro equity way, then we would recommend:

Early consultation and collaboration with indigenous organisations

- Removal of SA or the option of waiving certain criteria in the SA for Māori and Pacific populations recognising well documented decreased access to primary care, medications and monitoring of conditions
  Removal of the requirement in the SA to only access to one of the medications

Ngā mihi,

Dr Rachel Mackie
Chair of Te Akoranga a Māui

The Royal New Zealand
College of General Practitioners
Te Whare Tohu Rata o Aotearoa

27 November 2020

Dr Shirley Crawshaw
Medical Director of PHARMAC
PO Box 10254
The Terrace
Wellington 6143

By email: Withheld under section 9(2)(a)

Dear Shirley

I am writing to support the comments and points made by Dr Rachel Mackie regarding the funding of the new diabetic medications. This letter has already been e-mailed to PHARMAC. Dr Mackie is Chair of Te Akoranga a Māui who are an indigenous group within the Royal New Zealand College of General Practitioners, who represent over 200 Māori general practitioners.

The College agrees that issues around equitable access to these medications are central to diabetic outcomes in New Zealand. However, we strongly believe that this issue be resolved in a timely manner. We feel a further significant delay in access to these medications would be unacceptable and add to the already significant inequity Maori and Pacific have in relation to diabetes outcomes.

We look forward to progress on this issue.

Yours Sincerely

Bryan Betty
MBChB, FRNZCGP, FACRRM
Medical Director | Mātanga Hauora

From: Elena Saunders
Sent: Wednesday, 2 December 2020 9:39 am
To: PTAC Members <Withheld under section 9(2)(a)>
Cc: Scott Metcalfe <Withheld under section 9(2)(a)>; Geraldine MacGibbon (Withheld under section 9(2)(a)) <Withheld under section 9(2)(a)>
Subject: PHARMAC request for advice diabetes medicines Special Authority criteria

Dear PTAC,

As you are well aware, we have been working hard to consider the feedback we received in response to our consultation on the proposal to fund empagliflozin (with and without metformin), and dulaglutide. While the feedback was, in general, overwhelmingly supportive of the proposal to fund these medicines, some important questions were raised. While we tried to address the feedback in a rapid manner, ultimately the complexity and importance of the feedback resulted in us being unable to take the proposal to the Board for a decision at its 30 October meeting as we had originally planned

We have now completed our evaluation of the consultation feedback, and conducted some targeted engagement with some of the respondents where needed to ensure we understood the feedback and its context.

Based on our evaluation, we are considering amending the originally proposed Special Authority criteria to directly address a number of the different matters raised. These matters include, but are not limited to, concern that the criteria we had proposed would fall short of delivering on PHARMAC's (and indeed Aotearoa New Zealand's), aspirations for medicines access and health equity – in particular for Māori. We have taken this feedback on board and are considering a broader programme of work to improve the strength of our policies in relation to this matter. However, in the interim, we are also aware of the need to progress this transaction as quickly as we are able to - we are acutely aware of the need to make these medicines available to people in Aotearoa New Zealand as soon as possible

Once we have received your feedback on the amended criteria we intend to progress the proposal for a decision by the PHARMAC Board at the earliest available opportunity.

We would greatly appreciate your feedback on the proposed criteria below in terms of clinical workability. You can find the wording we originally proposed in the consultation.

Proposed Special Authority criteria

Initial application from any relevant practitioner Approvals valid without further renewal unless notified for applications meeting the following criteria:

All of the following:

1 Patient has type 2 diabetes; and
2. Any of the following:
   2.1. Patient is Māori or any Pacific ethnicity; or
   2.2. Patient has pre-existing cardiovascular disease or risk equivalent*; or
   2 3 Patient has an absolute 5 year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator; or

2 4 Patient has a high lifetime cardiovascular risk due to their young age at diagnosis of type 2 diabetes; or

2.5. Patient has diabetic kidney disease**; and

3. Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the use of at least one blood-glucose lowering medicine (eg metformin hydrochloride) for at least 3 months; and

4 Treatment will not be used in combination with a funded GLP 1 agonist

Note:
Criteria 2.1 – 2.5 define patients at high risk of cardiovascular or renal complications of diabetes
* Defined as: prior cardiovascular disease event (i.e. angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia.
** Defined as: persistent albuminuria (albumin:creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3-6 month period) and/or eGFR less than 60 mL/min/1.73m2 in the presence of diabetes, without alternative cause.

Questions to Committee

1. Do you consider the criteria proposed above would be workable in clinical practice?
   1.1. If not, what changes do you suggest?
2 Do you consider the criteria proposed above would broadly target the intended patient group for these medicines (i.e. those at highest need/with greatest capacity to benefit)?
3. What other comments do you have regarding the proposed criteria above?

Please let me know if there is any further information I can provide to assist in your consideration of these questions. If you are able to respond to me **by 12 noon on Monday 7th December** I would very much appreciate it

Ngā mihi nui,

Elena

Elena Saunders (she/her) | Therapeutic Group Manager

PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
Cell: Withheld under | DDI: Withheld under | P: +64 4 460 4990 | www pharmac govt nz

From: Elena Saunders
Sent: Wednesday, 2 December 2020 9:33 am
To: Diabetes Subcommittee <Withheld under section 9(2)(a)>
Cc: Scott Metcalfe <Withheld under section 9(2)(a)>; Geraldine MacGibbon (Withheld under section 9(2)(a)) <Withheld under section 9(2)(a)>
Subject: PHARMAC request for advice diabetes medicines Special Authority criteria

Dear Diabetes Subcommittee,

As you are well aware, we have been working hard to consider the feedback we received in response to our consultation on the proposal to fund empagliflozin (with and without metformin), and dulaglutide. While the feedback was, in general, overwhelmingly supportive of the proposal to fund these medicines, some important questions were raised. While we tried to address the feedback in a rapid manner, ultimately the complexity and importance of the feedback resulted in us being unable to take the proposal to the Board for a decision at its 30 October meeting as we had originally planned

We have now completed our evaluation of the consultation feedback, and conducted some targeted engagement with some of the respondents where needed to ensure we understood the feedback and its context.

Based on our evaluation, we are considering amending the originally proposed Special Authority criteria to directly address a number of the different matters raised. These matters include, but are not limited to, concern that the criteria we had proposed would fall short of delivering on PHARMAC's (and indeed Aotearoa New Zealand's), aspirations for medicines access and health equity – in particular for Māori. We have taken this feedback on board and are considering a broader programme of work to improve the strength of our policies in relation to this matter. However, in the interim, we are also aware of the need to progress this transaction as quickly as we are able to - we are acutely aware of the need to make these medicines available to people in Aotearoa New Zealand as soon as possible

Once we have received your feedback on the amended criteria we intend to progress the proposal for a decision by the PHARMAC Board at the earliest available opportunity.

We would greatly appreciate your feedback on the proposed criteria below in terms of clinical workability. You can find the wording we originally proposed in the consultation.

Proposed Special Authority criteria

Initial application from any relevant practitioner Approvals valid without further renewal unless notified for applications meeting the following criteria:

All of the following:

5 Patient has type 2 diabetes; and
6. Any of the following:
   6.1. Patient is Māori or any Pacific ethnicity; or
   6.2. Patient has pre-existing cardiovascular disease or risk equivalent*; or
   6 3 Patient has an absolute 5 year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator; or

6 4 Patient has a high lifetime cardiovascular risk due to their young age at diagnosis of type 2 diabetes; or

6.5. Patient has diabetic kidney disease**; and

7. Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the use of at least one blood-glucose lowering medicine (eg metformin hydrochloride) for at least 3 months; and

8 Treatment will not be used in combination with a funded GLP 1 agonist

Note:
Criteria 2.1 – 2.5 define patients at high risk of cardiovascular or renal complications of diabetes
* Defined as: prior cardiovascular disease event (i.e. angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia.
** Defined as: persistent albuminuria (albumin:creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3-6 month period) and/or eGFR less than 60 mL/min/1.73m2 in the presence of diabetes, without alternative cause.

Questions to Subcommittee

4. Do you consider the criteria proposed above would be workable in clinical practice?
   4.1. If not, what changes do you suggest?
5 Do you consider the criteria proposed above would broadly target the intended patient group for these medicines (i.e. those at highest need/with greatest capacity to benefit)?
6. What other comments do you have regarding the proposed criteria above?

Please let me know if there is any further information I can provide to assist in your consideration of these questions. If you are able to respond to me **by 12 noon on Monday 7th December** I would very much appreciate it

Ngā mihi nui,

Elena

Elena Saunders (she/her) | Therapeutic Group Manager

PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
Cell: Withheld under | DDI: Withheld under | P: +64 4 460 4990 | www pharmac govt nz

From: Elena Saunders
Sent: Wednesday, 2 December 2020 9:34 am
To: Cardiovascular Subcommittee <Withheld under section 9(2)(a)>
Cc: Scott Metcalfe <Withheld under section 9(2)(a)>; Geraldine MacGibbon (Withheld under section 9(2)(a)) <Withheld under section 9(2)(a)>
Subject: PHARMAC request for advice diabetes medicines Special Authority criteria

Dear Cardiovascular Subcommittee,

As you are well aware, we have been working hard to consider the feedback we received in response to our consultation on the proposal to fund empagliflozin (with and without metformin), and dulaglutide. While the feedback was, in general, overwhelmingly supportive of the proposal to fund these medicines, some important questions were raised. While we tried to address the feedback in a rapid manner, ultimately the complexity and importance of the feedback resulted in us being unable to take the proposal to the Board for a decision at its 30 October meeting as we had originally planned

We have now completed our evaluation of the consultation feedback, and conducted some targeted engagement with some of the respondents where needed to ensure we understood the feedback and its context.

Based on our evaluation, we are considering amending the originally proposed Special Authority criteria to directly address a number of the different matters raised. These matters include, but are not limited to, concern that the criteria we had proposed would fall short of delivering on PHARMAC's (and indeed Aotearoa New Zealand's), aspirations for medicines access and health equity – in particular for Māori. We have taken this feedback on board and are considering a broader programme of work to improve the strength of our policies in relation to this matter. However, in the interim, we are also aware of the need to progress this transaction as quickly as we are able to - we are acutely aware of the need to make these medicines available to people in Aotearoa New Zealand as soon as possible

Once we have received your feedback on the amended criteria we intend to progress the proposal for a decision by the PHARMAC Board at the earliest available opportunity.

We would greatly appreciate your feedback on the proposed criteria below in terms of clinical workability. You can find the wording we originally proposed in the consultation.

Proposed Special Authority criteria

Initial application from any relevant practitioner Approvals valid without further renewal unless notified for applications meeting the following criteria:

All of the following:

9 Patient has type 2 diabetes; and
10. Any of the following:
    10.1. Patient is Māori or any Pacific ethnicity; or
    10.2. Patient has pre-existing cardiovascular disease or risk equivalent*; or
    10 3 Patient has an absolute 5 year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator; or

10 4 Patient has a high lifetime cardiovascular risk due to their young age at diagnosis of type 2 diabetes; or

10.5. Patient has diabetic kidney disease**; and

11. Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the use of at least one blood-glucose lowering medicine (eg metformin hydrochloride) for at least 3 months; and

12 Treatment will not be used in combination with a funded GLP 1 agonist

Note:
Criteria 2.1 – 2.5 define patients at high risk of cardiovascular or renal complications of diabetes
* Defined as: prior cardiovascular disease event (i.e. angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia.
** Defined as: persistent albuminuria (albumin:creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3-6 month period) and/or eGFR less than 60 mL/min/1.73m2 in the presence of diabetes, without alternative cause.

Questions to Subcommittee

7. Do you consider the criteria proposed above would be workable in clinical practice?
   7.1. If not, what changes do you suggest?
8 Do you consider the criteria proposed above would broadly target the intended patient group for these medicines (i.e. those at highest need/with greatest capacity to benefit)?
9. What other comments do you have regarding the proposed criteria above?

Please let me know if there is any further information I can provide to assist in your consideration of these questions. If you are able to respond to me **by 12 noon on Monday 7th December** I would very much appreciate it

Ngā mihi nui,

Elena

Elena Saunders (she/her) | Therapeutic Group Manager

PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
Cell: Withheld under | DDI: Withheld under | P: +64 4 460 4990 | www pharmac govt nz

From: Elena Saunders
Sent: Wednesday, 2 December 2020 9:38 am
To: Nephrology Subcommittee <Withheld under section 9(2)(a)>
Cc: Scott Metcalfe <Withheld under section 9(2)(a)>; Geraldine MacGibbon (Withheld under section 9(2)(a)) <Withheld under section 9(2)(a)>
Subject: FW: PHARMAC request for advice diabetes medicines Special Authority criteria

Dear Nephrology Subcommittee,

As you are well aware, we have been working hard to consider the feedback we received in response to our consultation on the proposal to fund empagliflozin (with and without metformin), and dulaglutide. While the feedback was, in general, overwhelmingly supportive of the proposal to fund these medicines, some important questions were raised. While we tried to address the feedback in a rapid manner, ultimately the complexity and importance of the feedback resulted in us being unable to take the proposal to the Board for a decision at its 30 October meeting as we had originally planned

We have now completed our evaluation of the consultation feedback, and conducted some targeted engagement with some of the respondents where needed to ensure we understood the feedback and its context.

Based on our evaluation, we are considering amending the originally proposed Special Authority criteria to directly address a number of the different matters raised. These matters include, but are not limited to, concern that the criteria we had proposed would fall short of delivering on PHARMAC's (and indeed Aotearoa New Zealand's), aspirations for medicines access and health equity – in particular for Māori. We have taken this feedback on board and are considering a broader programme of work to improve the strength of our policies in relation to this matter. However, in the interim, we are also aware of the need to progress this transaction as quickly as we are able to - we are acutely aware of the need to make these medicines available to people in Aotearoa New Zealand as soon as possible

Once we have received your feedback on the amended criteria we intend to progress the proposal for a decision by the PHARMAC Board at the earliest available opportunity.

We would greatly appreciate your feedback on the proposed criteria below in terms of clinical workability. You can find the wording we originally proposed in the consultation.

Proposed Special Authority criteria

Initial application from any relevant practitioner Approvals valid without further renewal unless notified for applications meeting the following criteria:

All of the following:

13 Patient has type 2 diabetes; and
14. Any of the following:
    14.1. Patient is Māori or any Pacific ethnicity; or
    14.2. Patient has pre-existing cardiovascular disease or risk equivalent*; or
    14 3 Patient has an absolute 5 year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator; or

14 4 Patient has a high lifetime cardiovascular risk due to their young age at diagnosis of type 2 diabetes; or

14.5. Patient has diabetic kidney disease**; and

15. Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the use of at least one blood-glucose lowering medicine (eg metformin hydrochloride) for at least 3 months; and

16 Treatment will not be used in combination with a funded GLP 1 agonist

Note:
Criteria 2.1 – 2.5 define patients at high risk of cardiovascular or renal complications of diabetes
* Defined as: prior cardiovascular disease event (i.e. angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia.
** Defined as: persistent albuminuria (albumin:creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3-6 month period) and/or eGFR less than 60 mL/min/1.73m2 in the presence of diabetes, without alternative cause.

Questions to Subcommittee

10. Do you consider the criteria proposed above would be workable in clinical practice?
    10.1. If not, what changes do you suggest?
11 Do you consider the criteria proposed above would broadly target the intended patient group for these medicines (i.e. those at highest need/with greatest capacity to benefit)?
12. What other comments do you have regarding the proposed criteria above?

Please let me know if there is any further information I can provide to assist in your consideration of these questions. If you are able to respond to me **by 12 noon on Monday 7th December** I would very much appreciate it

Ngā mihi nui,

Elena

Elena Saunders (she/her) | Therapeutic Group Manager

PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
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From: Withheld under section 9(2)(g)(i)
Sent: Wednesday, 2 December 2020 9:44 AM
To: Elena Saunders <Withheld under section 9(2)(a)>
Subject: RE: PHARMAC request for advice diabetes medicines Special Authority criteria

Dear Elena

Sure that sounds fine.

In the discussions we had, and it has been a while since we saw it all through PTAC, my memory is that one of the issues was whether these chemicals should or should not be used in conjunction with insulin. While Metformin can be used with insulin the current SA is silent on whether these new agents can or cannot be used with insulin I know from clinical practice of our local diabetes teams that they are pretty slack in this respect; namely that some of their patients are on multiple oral medications and also on insulin; kind of defeating the point apart from Metformin.

I am not sure what advice was had from the various SC or whether we had a specific comment from PTAC on this

Regards

Withh

From: Elena Saunders <Withheld under section 9(2)(a)>
Sent: Wednesday, 2 December 2020 2:00 PM
To: Withheld under section 9(2)(g)(i)
Subject: RE: PHARMAC request for advice diabetes medicines Special Authority criteria

Kia ora Withh,

Thanks so much for getting back to us so quickly.

In response to your important point about combination therapy – we had the following from the Diabetes Subcommittee in March 2019:

The Subcommittee considered that if any additional antidiabetic agents were to be listed, they would be used as an add on to current therapy with metformin and/or sulphonylurea, ultimately providing an additional line of therapy prior to progression to insulin. The Subcommittee considered that upon progression to insulin use of the anti-diabetic agents was unlikely to be ceased.

If I am understanding your point correctly (and please forgive me if I am not) – the latest ADA EASD guidelines recommend the addition of insulin on top of these medicines if needed – and therefore I don't believe we would want to preclude the concomitant use of insulin. Furthermore, it is my understanding that the beneficial effects of these medicines are largely independent of glycaemic control, but glycaemic control does not become redundant with their use if that makes sense.

In terms of CUA and budgetary impact analysis, we have assumed (likely in a fiscally conservative fashion), that patients remain on all their other anti diabetic medicines throughout, and continue on to insulin if not already taking it (albeit with a potential for some delay to insulin factored in)

Hope that makes sense – let me know if I have taken the wrong end of the stick!

Ngā mihi,

Elena

Elena Saunders (she/her) | Therapeutic Group Manager

PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
Cell: Withheld under | DDI: Withheld under | P: +64 4 460 4990 | www.pharmac.govt.nz

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From: Withheld under section 9(2)(g)(i)
Sent: Thursday, 3 December 2020 7:56 am
To: Elena Saunders <Withheld under section 9(2)(a)>
Subject: RE: PHARMAC request for advice - diabetes medicines Special Authority criteria

Sure, I just wasn't sure what discussions had been had, it is relevant to much older discussions we had where one of the points the SC was emphasising was using these in people at high risk of hypoglycaemia; which they then couldn't define, this being an argument for not using them with insulin. I am not sure we or the SC has seen any evidence about using two/three/four medications and insulin in terms of glycemic control versus just insulin with metformin or insulin alone. As you say the arguments become redundant with the evolving evidence of improved overall survival and/or components of this

Regards

Withh

From: Withheld under section 9(2)(g)(i)
Sent: Wednesday, 2 December 2020 1:21 pm
To: Elena Saunders <Withheld under section 9(2)(a)>
Cc: Withheld under section 9(2)(g)(i); PTAC Members <Withheld under section 9(2)(a)>; Scott Metcalfe <Withheld under section 9(2)(a)>; Geraldine MacGibbon <Withheld under section 9(2)(a)>
Subject: Re: PHARMAC request for advice diabetes medicines Special Authority criteria

Dear Elena,

I am not sure this goes far enough to address equity If the idea is to facilitate access of these patients to Maori/Pacfika, can I suggest you consider the following:

1. Patient has type 2 diabetes; and
2. Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the use of at least one blood glucose lowering medicine (eg metformin hydrochloride) for at least 3 months; and any of the following:
    a. Patient has pre-existing cardiovascular disease or risk equivalent*; or
    b Patient has an absolute 5 year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator; or
    c. Patient has a high lifetime cardiovascular risk due to their young age at diagnosis of type 2 diabetes; or
    d. Patient has diabetic kidney disease**; or
3. Patient is Māori or any Pacific ethnicity; and
    a Is at risk of cardiovascular disease; and
4. Treatment will not be used in combination with a funded GLP-1 agonist

This would mean Māori/Pacifika only need to be diabetic and have a risk of CVS disease, without the need for having used a previous agent, or having an HbA1c. Would that be too far?
Kind Regards,

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Withheld under section 9(2)(g)(i)
Withheld under section 9(2)(a)

From: Withheld under section 9(2)(g)(i)
Sent: Wednesday, 2 December 2020 1:23 pm
To: Elena Saunders <Withheld under section 9(2)(a)>
Subject: RE: PHARMAC request for advice diabetes medicines Special Authority criteria

Love it Elana!
This really throws the cat among the pigeons. It will be a first to prescribe along racial lines and that is political dynamite. There is sufficient evidence to do this but I am sure there will be a bit of hoo-ha over it. Everyone will flout the rules, basically because it is difficult to define Maori or Pacific ethnicity (how many generations back do you go, can you call yourself Maori like Mrs Tamaki has?). We assume that ethnicity equates with poverty, access etc (as well as institutional racism) but many will cry foul because they are also poor and live rurally or poorly traced ancestry.
It is all about how it is presented to the public and practitioners and supported from government.

Am I, as a fifth generation kiwi, a Pacific Islander?
Is ethnicity recorded in patient notes... what about all those who report only dominant ethnicity, but have others?
I will follow this discussion with interest.

Withh

From: Withheld under section 9(2)(g)(i)
Sent: Wednesday, 2 December 2020 6:18 PM
To: Elena Saunders <Withheld under section 9(2)(a)>
Subject: RE: PHARMAC request for advice diabetes medicines Special Authority criteria

Thank you

I have read the new proposed Special Authority Criteria for Empagliflozin and Duaglutide.

1. Yes these criteria would be workable in practice. The set out may be a little ambiguous. I take it that the person must meet criteria 1, 3 and 4 and one of the criteria from section 2, 2.1 – 2.5
2 Yes I believe these criteria will broadly target the intended patient group who will benefit most I cannot see any age exclusion and don't believe that there should be.

Other comments:
I think there will be little difference in practice using the updated criteria, although the emphasis on Māori and Pacific ethnicities is appropriate I am sure you have all the data about increased burden of chronic diseases, higher CVS risk, increased rates of diabetes and progression to ESKF in these populations

I have 10 years of experience in a Diabetes and CKD clinic for adults with diabetes and CKD 2 and 3 The proportion of those who identify as Māori is more than double that of the local population and all would have meet the criteria for an SGLT2i under your previous criteria

My other comment is the high number of teenagers with Type 2 Diabetes which is predicted to increase This group is presenting with early onset of proteinuria and rapid progression of CKD. This is thought to be influenced by in utero exposure to hyperglycaemia with genetic / epigenetic interplay. It will be important that the safety in pregnancy data is updated as it becomes available

I assume that the criteria allowing either an SGLT2i or an GLP-1 agonist but not both is on a cost basis? While they both have evidence for reducing cardiovascular risk the mechanisms are different with the GPL-1 agonist reducing atherosclerotic CVS related disease and the SGLT2i reducing the incidence and hospitalisation for Congestive Cardiac Failure. So they are complementary, though I do not know of studies yet that look to see if the CVS benefits of the 2 agents are additive or enhance the outcomes further.

Yours sincerely

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From: Elena Saunders
Sent: Thursday, 3 December 2020 9:26 am

To: Withheld under section 9(2)(g)(i)
Subject: RE: PHARMAC request for advice diabetes medicines Special Authority criteria

Thanks so much for this helpful and considered response Withheld Yes – you are right – the exclusion of concomitant use of the two modes is largely on a cost basis, and due to the fact we have not had a funding request for combination use and therefore have not formally considered the cost effectiveness etc of the combination. This is something we will look into, but for now we weren't able to remove that criterion.

Ngā mihi,

Elena

Elena Saunders (she/her) | Therapeutic Group Manager

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From: Withheld under section 9(2)(g)(i)
Sent: Wednesday, 2 December 2020 11:10 AM
To: Elena Saunders <Withheld under section 9(2)(a)>; Diabetes Subcommittee <Withheld under section 9(2)(a)>
Cc: Scott Metcalfe <Withheld under section 9(2)(a)>; Geraldine MacGibbon <Withheld under section 9(2)(a)>
Subject: RE: PHARMAC request for advice diabetes medicines Special Authority criteria[EXTERNAL SENDER]

Mōrena Elena,

thanks for progressing this important piece of work and also for giving us the opportunity to provide feedback My feedback reflects recent conversations with local diabetes clinicians from secondary and primary care.

Questions to Subcommittee

13. Do you consider the criteria proposed above would be workable in clinical practice?
    Largely workable – the looseness of the wording around 2.4, should allow many high needs, high risk groups (e.g. Indian; migrant communities) access to these medications, in a way that seems 'fair'.
    13 1 If not, what changes do you suggest? N A see below
14. Do you consider the criteria proposed above would broadly target the intended patient group for these medicines (i.e. those at highest need/with greatest capacity to benefit)?
    As above
15. What other comments do you have regarding the proposed criteria above?
    A) You will be aware of the discussions the original proposal generated around definitions of equity and fairness and also the tensions that might exist between equity from a Treaty partner perspective, versus a much broader view of equity, fairness and institutional racism, for ethnic populations other than Māori. This debate was explored further following the meeting arranged by the Maurice Wilkins Centre, last month This in turn has (at least locally) generated some confusion around the inclusion of Pacific peoples in ***2.1***. In other words, is statement 2 1 related mainly to the Treaty? If yes, then should Māori be the only Treaty partner mentioned, maybe with the inclusion of Pacific peoples in a separate statement e.g. statement 2.2 might be around access for those of Pacific ethnicity. If the intention was *not* to reference Treaty obligations, either directly or indirectly, then why not?
    B) Whatever wording is used, there will be some questioning by some patients for the reasoning behind the wording Clinicians don't want to spend a lot of clinical time 'justifying' criteria to patients, that they may themselves not fully understand. If there was some publicly available justification by PHARMAC for the wording and this justification is readily available for patients who seek 'explanations', maybe by providing this online as a Q & A, this would save clinical time.
    C) There also seems to be local confusion around interpretation of the wording (Section 3) … *despite the use of at least one blood glucose lowing medication for at least 3 months*. Assume this might include insulin and not just tablet treatment? If a patient is metformin intolerant, then they might for example need to use insulin for 3/12, before trialling an SGLT2i? Assume also that a patient could trial an ultra low dose medication for 3/12, for example 2.5mg glipizide before dinner to use only if eating a large dinner, that might result in reaching inclusion criteria? If after 3/12, HbA1c criteria (>53 mmol/mol) are met in this scenario, then it is OK to start an SGLT2i?

D) Assume it will be OK to switch from a funded SGLT2i (anticipating they will be the 'first cab off the rank'), to a GLP 1RA once this becomes available? In other words, how to ensure that patients who use funded SGLT2i and who subsequently reach an of HbA1c <53mmol/mol but might want to trial a medication with a greater weight loss effect, are not disadvantaged in terms of future access to GLP 1RA?

E) 'Legacy' issues around patients who are currently self funding dapagliflozin (and maybe GLP1RA – but numbers are low). How will these be addressed? The patients I have who are self-funding dapagliflozin come from very diverse backgrounds. Many are from high risk, high needs ethnic groups and they struggle to self-fund. Many are self-funding as part of a treatment package aimed at ensuring they retain occupational driving status. It would be unfair not to work through what these legacy issues might look like in practice. For example, if the patient went onto dapagliflozin, and at the time of dapagliflozin initiation would in effect have fulfilled the proposed 'new' criteria, but HbA1c has now come down to <53mmol/mol, should they be allowed access? I believe they should be allowed access to a funded SGLT2i.

Ngā mihi nui,

Withhe

From: Elena Saunders <Withheld under section 9(2)(a)>
Sent: Wednesday, 2 December 2020 2:38 PM
To: Withheld under section 9(2)(g)(i)
Cc: Scott Metcalfe <Withheld under section 9(2)(a)>; Geraldine MacGibbon <Withheld under section 9(2)(a)>
Subject: RE: PHARMAC request for advice diabetes medicines Special Authority criteria[EXTERNAL SENDER]

Kia ora Withhe,

Thanks for your (as always!) considered response – and I picked up your voice message as well.

I believe I understand the point about equity versus Tiriti obligations – and agree this is an important distinction. I think clear communication (as you've suggested in your point B) below), will be the best way to articulate the rationale covering these points

In relation to the requirement to trial something prior- this could be any glucose lowering medication – including insulin The metformin is retained as an "eg" but it wouldn't need to be metformin. **Do you have any suggestion on how we could amend the wording to make that more clear?**

Regarding your point D), the two modes of action could be used sequentially under the proposed criteria – just not in parallel (ie combination).

Finally – E) – we generally aren't able to directly consider self funding of medicines in our funding decisions – you can appreciate the equity challenges this in itself can raise. In the type of case described below at this point we would need to handle this via a SA waiver mechanism whereby if the person would have met the criteria prior to commencing the self funded treatment then we

would consider approving and SA waiver. **Do you have a feel for how many people would likely be in this clinical position (rough estimate of course)?**

Thanks again,

Elena

Elena Saunders (she/her) | Therapeutic Group Manager

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From: Withheld under section 9(2)(g)(i)
Sent: Wednesday, 2 December 2020 3:23 pm
To: Elena Saunders <Withheld under section 9(2)(a)>
Cc: Scott Metcalfe <Withheld under section 9(2)(a)>; Geraldine MacGibbon <Withheld under section 9(2)(a)>
Subject: RE: PHARMAC request for advice diabetes medicines Special Authority criteria[EXTERNAL SENDER]

Thanks Elena,

1. Trial of anti-diabetic agent prior to 'new' medications. May I suggest you try and get a feel from primary care prescribers including ***nurse prescribers*** about how they see this, but one option would be to replace the wording: *Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the use of at least one blood-glucose lowering medicine (eg metformin hydrochloride) for at least 3 months;* with something such as *..despite the regular use of at least one anti-diabetic agent (e.g. metformin, insulin) in the previous 3/12*...if this is indeed what you mean. The reason for considering a change from *medication* to *agent* is that sometimes folk automatically think *medication = tablets*. Also 'blood glucose lowering agent' – some folk think this references hypoglycaemic agents i e those agents that might cause low blood sugars (hypoglycaemia) if used as monotherapy.. By talking about the *previous* 3/12, I think this reduces any ambiguity around when the 3/12 period had to be – taking things to extremes, it might for example have been insulin in the last trimester of pregnancy, 10 years previously
2. Self-funded dapagliflozin. Have heard a number bouncing around of 1,400 self-funded patients in NZ, but have no way of verifying this myself. Am not sure what the prescribing practices are outside our own centre, but locally most will have CV risk factors that fit with proposed criteria, many are Māori and most will not have reached the HbA1c target <53mmol/mol despite the use of dapagliflozin, so it will be easy for practitioners to fill in the proposed SA paperwork, for this subgroup of patients who are already on dapagliflozin. Would think that only say <30% locally, might be sufficiently 'problematic' that they need to be considered on 'grandfathering' criteria e.g. would need a SA waiver. Assume also that patients coming from say Australia on SGLT2i medications, funded through their PBS system, would be assessed in a similar way?

Hope that helps a bit,

Ngā mihi nui, Withhe

From: Withheld under section 9(2)(g)(i)
Sent: Thursday, 3 December 2020 9:47 am
To: Elena Saunders <Withheld under section 9(2)(a)>
Subject: Re: PHARMAC request for advice diabetes medicines Special Authority criteria

Kia ora Elena,

1. I think this is a significant improvement on the last criteria. As a GP I can certainly see this as very workable, especially as lifetime rx without requiring constant renewal.
2 I think that the inclusion criteria will enable us to target young diabetic patients such as Maori and Pacific patients in 30s, 40s and deliver significant lifetime benefit., alongside those who have already suffered complications It is a far better approach than one that favours those who meet disease specific criteria due to being able to afford GP appointments for diabetic review etc.
3 I applaud Pharmac for the changes to these meds, I believe they will be significant in addressing health and equity outcomes in NZ.

Kind regards,
Withheld under

From: Withheld under section 9(2)(g)(i)
Sent: Thursday, 3 December 2020 10:06 am
To: Elena Saunders <Withheld under section 9(2)(a)>
Cc: Scott Metcalfe <Withheld under section 9(2)(a)>; Geraldine MacGibbon <Withheld under section 9(2)(a)>
Subject: RE: PHARMAC request for advice diabetes medicines Special Authority criteria[EXTERNAL SENDER]

Thanks elena see below
Questions to Committee

1. **Do you consider the criteria proposed above would be workable in clinical practice?**
   I think so I think you need to define the "young age" is that <50 ?40??
   1.1. If not, what changes do you suggest?
2. **Do you consider the criteria proposed above would broadly target the intended patient group for these medicines (i.e. those at highest need/with greatest capacity to benefit)? y**es
3. What other comments do you have regarding the proposed criteria above? nil

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From: Withheld under section 9(2)(g)(i)
Sent: Thursday, 3 December 2020 12:51 pm
To: Elena Saunders <Withheld under section 9(2)(a)>; PTAC Members <Withheld under section 9(2)(a)>
Cc: Scott Metcalfe <Withheld under section 9(2)(a)>; Geraldine MacGibbon <Withheld under section 9(2)(a)>
Subject: RE: PHARMAC request for advice diabetes medicines Special Authority criteria Wit

Elana et al, thoughts below;

Questions to Committee

16. Do you consider the criteria proposed above would be workable in clinical practice?
    16 1 If not, what changes do you suggest?
    YES Seem workable
17. Do you consider the criteria proposed above would broadly target the intended patient group for these medicines (i e those at highest need/with greatest capacity to benefit)?
    I missed the Nov PTAC and discussion re Equity which presumably assisted in the development here.
    I do have a concern that Equity is challenged by the blanket inclusion of ethnic group as a criteria which could set precedent for every/many agents with SA access. I do not know ethnicity based evidence of benefit in this data.
    Also, as far as I am aware Inequity in many NZ settings is about decisions to initiate appropriate medicines which the SA access will not resolve.

    My notion of addressing Inequity is better described by adjusted access criteria reflective of risks e.g. lower age of access for bowel screening in Maori who have lower overall life expectancy and I do not know the evidence in this drug/patient group well enough to suggest a suitable "equity correction" component.

18. What other comments do you have regarding the proposed criteria above?
    Feels like I would re-order the elements in 2.1-5 to reflect evidence in support of each element which would perhaps see ethnicity last on the list?

    Assuming these may all have been canvassed and resolved – I remain comfortable as they read

Nga mihi
With

From: Withheld under section 9(2)(g)(i)
Sent: Thursday, 3 December 2020 1:57 PM
To: Elena Saunders <Withheld under section 9(2)(a)>; Diabetes Subcommittee <Withheld under section 9(2)(a)>
Cc: Scott Metcalfe <Withheld under section 9(2)(a)>; Geraldine MacGibbon <Withheld under section 9(2)(a)>
Subject: Re: PHARMAC request for advice diabetes medicines Special Authority criteria

Kia ora and thanks for asking for feedback
Firstly, wow!
This is a pro-equity approach.
I have a few comments:

1. Workability: in GP computer systems we routinely record ethnicity data and utilise it when using cardiovascular risk calculators already. We do need to have "prioritised ethnicity", so that if someone has whakapapa Maori or Samoan ancestry, it might be recorded as Ethnicity 2 or 3 in the computer and only Ethnicity 1 is displayed prominently on the screen. In research, and in census data, Maori/ Pacific is shifted to Ethnicity 1 It is unclear in mainstream general practices how often (or if) this is implemented. The "high lifetime risk due to young age" criterion is pretty vague, with lots of room for clinician judgment which will vary from prescriber to prescriber I don't have a good suggestion though about how to tighten it up other than to stipulate an age (like diagnosis under a certain age - don't know if it should be 25, 30, 35 or 40??).
2 Reach: The Indian population is at higher risk of poor cardiovascular and renal outcomes. I don't have a feel for the size of this population
3 Other comments: Implementation I know that NZSSD have a NZ guideline including these medications ready to roll. There will need to be some implementation work targeting practices with high numbers or Maori/Pacific (basically the iwi providers, Union Health Clinics and very-low-cost-access clinics) who are likely to be high prescribers. Re: education and safety

Withh
(ps well done!)

From: Elena Saunders <Withheld under section 9(2)(a)>
Sent: Thursday, 3 December 2020 2:09 PM
To: Withheld under section 9(2)(g)(i)
Subject: RE: PHARMAC request for advice diabetes medicines Special Authority criteria

Thanks so much Withh

Can I just clarify one point are you saying you think we should state "prioritised ethnicity" in the criteria themselves?

Elena Saunders (she/her) | Therapeutic Group Manager

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From: Withheld under section 9(2)(g)(i)
Sent: Thursday, 3 December 2020 2:11 pm
To: Elena Saunders <Withheld under section 9(2)(a)>
Subject: Re: PHARMAC request for advice diabetes medicines Special Authority criteria

No I think that would be controversial wording and might be misinterpreted I think it's a matter for general practice comms (via PHOs) to make sure their ethnicity data is robustly recorded (so that Maori or Pacific are recorded as number 1, not 2 or 3 on the system). So that the intended population doesn't miss out

Withh

From: Withheld under section 9(2)(g)(i)
Sent: Thursday, 3 December 2020 6:42 pm
To: Elena Saunders <Withheld under section 9(2)(a)>
Subject: Re: PHARMAC request for advice diabetes medicines Special Authority criteria

Hi Elena,
Thankyou for this request. There has been a great deal of discussion around this.
I Think the wording would work in clinical practice. Although I do think open access would be best to look at equity.
Can you also look at who can do special authority? I know that nurse prescribers can not prescribe these medications at the moment but the nursing council is looking at that I understand that Pharmac is in control of that? It would make it easier for nurses to prescribe these medications and again get more patients onto these medications

Thanking you
Withheld under

From: Withheld under section 9(2)(g)(i)
Sent: Friday, 4 December 2020 11:26 am
To: Elena Saunders <Withheld under section 9(2)(a)>; PTAC Members <Withheld under section 9(2)(a)>
Cc: Scott Metcalfe <Withheld under section 9(2)(a)>; Geraldine MacGibbon <Withheld under section 9(2)(a)>
Subject: RE: PHARMAC request for advice diabetes medicines Special Authority criteria

Kia ora,

I completely endorse the intent of 2 1, but am concerned as to how this will "actually" be implemented.
How do we decide who is Maori or Pacific?
I am concerned, that if we limit it to those who have this ethnicity attached to NHI, we miss out some.
Conversely, if this is a mechanism to obtain this class of medicines, how we will know if someone "claims" to be Maori/Pacific (or is this a risk we take)?
At the meeting, the Australian model of "Closing the Gap" was discussed Would this type of system not be a more comprehensive way to address access equity.

Again, supportive of intent, but think there may be some fishhooks at the prescriber interface.
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From: Withheld under section 9(2)(g)(i)
Sent: Friday, 4 December 2020 5:13 pm
To: Elena Saunders <Withheld under section 9(2)(a)>
Subject: Re: PHARMAC request for advice diabetes medicines Special Authority criteria

Kia ora Elena

I appreciate PHARMAC's commitment to prioritising the rapid funding of these medications for type 2 diabetes, and in taking feedback about the SA criteria seriously. Any widening of SA criteria towards permitting [and guiding] the use of these medications as per evidence-based guidelines is much needed

- The 2.4 criterion is a welcome addition to the SA criteria, and the way in which it is worded (without any arbitrary age threshold) provides sufficient clinical discretion to prescribing these medications to many who could benefit, including those of Pacific, Indian and Māori ethnicities who develop type 2 diabetes at a younger age. Only rationing and budgetary constraints would underpin any decision to state an age of 25 or 30 years of onset, as some clinicians may interpret young age of onset to be below 45 years or similar!

- The much debated 2 1 criterion "*Patient is Maori or any Pacific ethnicity*" is not something I personally have any issues with, but I can sense a divide in the clinical and public reaction to this, which may create considerable professional issues and public outcry On the basis of workability, there are some very loaded conversations to be had with our patients about their ethnicity, if the stakes for accessing medications are based on this self-defined status (and perceived benefits which are likely to be overhyped by the accompanying media). The potential for superior health outcome benefits for Maori or Pacific people with type 2 diabetes, directly arising from including this criterion are **miniscule** The main "advantage" to Maori or Pacific people in being able to access these medications according to the propose criteria will be for those who are diagnosed with T2D above the age of ~40, and have HbA1c >53 but do not have significant renal, CVD or HF risk, in whom the benefits on absolute risk of CVD/renal adverse health outcomes will therefore be very low The main benefit that I can see from this ethnicity criterion is political favour and this will set a clear precedent for this criterion to be considered in all other medicine funding decisions to come. From a scientific and clinical basis, I would have to argue that the other SA criteria are sufficient for targeting the intended patient group for these medicines and that ethnicity is not a sufficient proxy for either those at highest need or those with greatest capacity to benefit. If there are Treaty issues to consider, then perhaps this ethnicity criteria should only include Māori.

- While perhaps not the primary intention of SA criteria, these will likely be used by non specialists (eg: GP's) as a guide to appropriate prescribing, hence *the inclusion of the criterion "treatment is to be used in conjunction with other measures to reduce cardiovascular risk in line with current standard of care"* would assist with the reminder to optimise CVD risk management Unfortunately optimal CVD and renal risk management is variably achieved across different health care providers. This criterion was in previous versions of the SA criteria but was probably removed for conciseness However, much data shows that there is a systemic problem for prescribing guideline recommended therapies that is not SA limited or differential by ethnicity: Testsafe data analysed by Wing Cheuk Chan shows that for preventing renal function decline, the proportion of people with diabetes who are not on guideline ACEi/ARB despite microalbuminuria being present is 22% for European, 21% for Maori and 20% for Pacific (21% overall)

I do hope this feedback helps you in your deliberation for funding as PHARMAC is in the unenviable position of doing this very difficult task.

BTW – are there any legal definitions of how ethnicity status switches are made or ratified as this is a Q I have received?

All best wishes

Withh

From: Withheld under section 9(2)(g)(i)
Sent: Sunday, 6 December 2020 10:34 pm
To: Elena Saunders <Withheld under section 9(2)(a)>
Subject: Re: PHARMAC request for advice diabetes medicines Special Authority criteria

Hi Elena,

My view was that these medications should be freely available to all with T2DM and I know that was PHARMAC's ideal too.

Given that this doesn't apepar to be possible then I think the initial SA propsal was an appropriate stop gap until wider access can be funded.

To be honest, I don't think that 2.1 will make much difference to access but at least Māori and Pasifika will be able to gain acces more easily. This is clear discriminatory against other ethnicities, in particular Asian, who have in creasined risk of T2DM and may well need early access to medications. In reality, they may well fulfil other criteria but I would expect that there may be some creative interpretation of the SA criteria

Regards

Withheld

From: Withheld under section 9(2)(g)(i)
Sent: Tuesday, 8 December 2020 12:37 pm
To: Elena Saunders <Withheld under section 9(2)(a)>; Cardiovascular Subcommittee <Withheld under section 9(2)(a)>
Cc: Scott Metcalfe <Withheld under section 9(2)(a)>; Geraldine MacGibbon <Withheld under section 9(2)(a)>
Subject: RE: PHARMAC request for advice diabetes medicines Special Authority criteria

Dear Elena

Section 2 1 should be carefully considered, as it has wider implications for all Pharmac special authority criteria.

1 What is the aim? Is it to better meet Treaty of Waitangi obligations? If so, the criteria should specify Maori. Is it to better allocate resources to ethnicities which are disproportionately affected by diabetes, heart and renal disease, often at a young age? If so, Maori and Pacific peoples certainly qualify, but so do those of NZ Indian ethnicity If it is to overcome the barrier which Special Authority forms cause in access to expensive drugs, all those who are less educated and from lower socio economic groups are likely disadvantaged
2. Will it increase Maori and Pacific access to empagliflozin? I suspect not, as Maori and Pacific peoples with poorly controlled diabetes tend to have multiple other co morbidities and risk factors obesity, smoking, hypertension and present late to the health sector. Most would qualify under sections 2.2-2.5 anyway

Section 2.4 lacks rigour. What is "young age at diagnosis?" Do all younger patients become immediately eligible? Probably best to specify an age threshold eg onset before 30 years of age. The Diabetes Subcommittee are best placed to advise on the appropriate cutoff.

Since empagliflozin was reviewed from the perspective of a diabetes medication, evidence has continue to accrue on their heart failure and renal benefits in those without diabetes. This needs early consideration, as some of these patients (especially those with non diabetic renal disease) may gain a greater benefit than some of those with diabetes ie. there may not be optimal alignment of highest need/ greatest capacity to benefit.

Regards
Withheld under

From: Elena Saunders <Withheld under section 9(2)(a)>
Sent: Monday, 7 December 2020 1:56 PM
To: Withheld under section 9(2)(g)(i); Withheld under section 9(2)(g)(i)
Cc: Scott Metcalfe <Withheld under section 9(2)(a)>
Subject: Urgent question regarding SA criteria young onset diabetes[EXTERNAL SENDER]
Importance: High

Dear Withh and Withhe,

I am in the final stages of the SA criteria for the diabetes agents. As you may have seen from some feedback received (and indeed have pointed out yourselves) – the criterion regarding young onset diabetes is somewhat ambiguous. We are hesitant to put a hard cut off on this, but I am wondering whether the following would capture the intent of identifying those individuals who, through virtue of their young age at diagnosis are at a significantly high lifetime risk of cardiovascular and/or renal complications from type 2 diabetes;

> 16.1. Patient has a high lifetime cardiovascular risk due to their young age at diagnosis (e.g. 17 years or younger) of type 2 diabetes; or

This is instead of the previous iteration of:

> 1 1 Patient has a high lifetime cardiovascular risk due to their young age at diagnosis of type 2 diabetes; or

Please could you let me know by return email whether or not this would be workable in clinical practice, and appropriately capture the intended group?

Ngā mihi,

Elena

Elena Saunders (she/her) | Therapeutic Group Manager

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From: Withheld under section 9(2)(g)(i)
Sent: Monday, 7 December 2020 2:31 PM
To: Elena Saunders <Withheld under section 9(2)(a)>; Withheld under
Withheld under section 9(2)(a) and
Cc: Scott Metcalfe <Withheld under section 9(2)(a)>
Subject: RE: Urgent question regarding SA criteria young onset diabetes[EXTERNAL SENDER]

Kia ora Elena,

I much prefer the 'loose wording' of the previous (not current) iteration

Taking a 'youth centric' view of criteria, it is often difficult to know in individual patients, when the onset of type 2 diabetes has occurred. This is especially true if there is no systematic screening of children with obesity living within a complex, socially deprived environment. As an example, was triaging a GP referral letter this morning about a 19 year old non European NZ permanent resident

with type 2 diabetes and an immigrant background. Going back into the mists of time to come up with a year of biochemical laboratory diagnosis would be difficult, also the time period when a biochemical abnormality was first noted, is unlikely to reflect the time of disease onset.

Taking an evidence based approach, why an age of <17 years, why not say <25 years? Maybe include 'youth' in the definition, which is often defined as 15 24 years of age but has a somewhat vague upper age limit.

If you wanted access for those with very early onset type 2 DM who happened not to be of Māori or Pasifika ethnicity, maybe the wording might be 'semi-loose' e.g.

1.1. *Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a youth;*

Also, as previously mentioned, the reason I liked the initial 'loose' wording, was that it allowed populations who might be at increased risk of CV disease partly because of their disadvantaged socioeconomic background, to have some chance of accessing 'new' diabetes medications. Personally, I'd therefore prefer the wording to be along these lines: *Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult;*

I do however recognise that my second set of comments may not be the focus of the current e-mail! Also, I believe you have to have some faith that prescribers will 'do the right thing' from an equity perspective and follow the principles behind criteria, however vague the wording.

Ngā mihi,

Withhe

On 7/12/2020, at 2:48 PM, Elena Saunders <Withheld under section 9(2)(a)> wrote:

Thanks Withhe – this is really helpful

Elena

Elena Saunders (she/her) | Therapeutic Group Manager

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From: Withheld under section 9(2)(g)(i)
Sent: Monday, 7 December 2020 3:45 pm
To: Elena Saunders <Withheld under section 9(2)(a)>
Cc: Withheld under section 9(2)(g)(i); Scott Metcalfe <Withheld under section 9(2)(a)>
Subject: Re: Urgent question regarding SA criteria young onset diabetes[EXTERNAL SENDER]

Dear Elena,

I'd agree that the looser wording is better but if you need to specify an age it should be older than 17. The disease process had often been going on for some time prior to diagnosis so defining onset, which would be better, would be tricky.

Cheers
Withh
Sent from my I phone