Catalogue of Evidence in relation to Diabetes RFP SA criteria

	Title	Author(s) & Source	Links	Outline
1	Metformin adherence in patients with type 2 diabetes and its association with glycated haemoglobin levels.	Chepulis L, Mayo C, Morison B, Keenan R, Lao C, Paul R, Lawrenson R **J PRIM HEALTH CARE 2020**;12(4) doi:10.1071/HC20043 5 November 2020	 2020 Chepulis et al - Metformin adherer https://www.publish.csiro.au/hc/HC20043	Ethnic disparity in metformin use appears to be due to fewer prescriptions for Māori than for New Zealand Europeans. A medication ratio of $0.8 (80% of days covered) is associated with a reduction in HbA1c of 4.8 and 5.0 mmol/mol in all and Māori patients, respectively.
2	Ethnic differences in mortality and hospital admission rates between Māori, Pacific, and European New Zealanders with type 2 diabetes between 1994 and 2018: a retrospective, population-based, longitudinal cohort study	Yu D, Zhao Z, Levi Osuagwu U, Pickering K, Baker J, Cutfield R, Orr-Walker B J, Cai Y, Simmons D **Lancet Glob Health** 2020 Published Online October 15, 2020 https://doi.org/10.1016/S2214-109X(20)30412-5	 2020 Yu et al - Ethnic differences in https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(20)30412-5/fulltext	Type 2 diabetes affects Indigenous and non-European populations disproportionately, including in New Zealand, where long-term temporal trends in cause-specific clinical outcomes between Māori, Pacific, and European people remain unclear. We aimed to compare the rates of mortality and hospital admission between Māori, Pacific, and European patients with type 2 diabetes in Auckland, New Zealand, over a period of 24 years.
3	New Zealand may finally get funded access to diabetes drugs which reduce cardiovascular events and progression of kidney disease: an audit of proposed PHARMAC criteria compared with international guidelines.	Vitz M, Moss B, Ward H, Soma P, Isichei-Kizito J, Hall R, Krebs J **NZMJ 9** October 2020, Vol 133 No 1523 ISSN 1175-8716	 2020-10 Vitz et al NZMJ.obr https://www.nzma.org.nz/journal-articles/new-zealand-may-finally-get-funded-access-to-diabetes-drugs-which-reduce-cardiovascular-events-and-progression-of-kidney-disease-an-audit-of-proposed-pharmac-criteria-compared-with-international-guidelines	Sodium-glucose cotransporter-2 (SGLT-2) inhibitors and glucagon-like peptide-1 (GLP-1) agonists are classes of medications shown to reduce cardiovascular events and slow decline in renal function in people with type 2 diabetes (T^2DM). They are recommended for many people as second-line agents after metformin by the American Diabetes Association (ADA) and European Association for the Study of Diabetes (EASD). PHARMAC have proposed criteria for funding in New Zealand. This clinical audit compares which patients would be eligible for treatment under each criterion.
4	Understandings of disease among Pacific peoples with diabetes and end-stage renal disease in New Zealand	Schmidt-Busby J, Wiles J, Exeter D, Kenealy T **Health Expect**. 2019; 22(5): 1122-31	 2019 Schmidt-Busby et al - Understandin https://pubmed.ncbi.nlm.nih.gov/31368649/	Given diabetes is prevalent across successive generations of Pacific Island families, health providers need to consider an individual's understanding and underlying contexts for 'why they are understood in that way'. This study found that family perceptions of diabetes across generations reinforced participants' low engagement in diabetes self-management. All 16 families experienced simultaneous diabetes across multiple generations and interviews reveal indications of ESRD following the same pattern. Findings reveal (mis)understandings about diabetes stemmed from education and communication from health providers that were insufficiently connected to the individual. If misunderstandings are embedded in the family, then

	Title	Author(s) & Source	Links	Outline
				efficient and effective re-education needs to address both family perceptions and individual health needs in unison
5	Six new studies about diabetes: what can we learn that might benefit Māori and Pacific people?	Kenealy T W, Sheridan N F, Orr-Walker B J **NZMJ 17** February 2017, Vol 130 No 1450 ISSN 1175-8716	 2017 Kenealy et al - Six new studies abo https://www.nzma.org.nz/journal-articles/six-new-studies-about-diabetes-what-can-we-learn-that-might-benefit-maori-and-pacific-people	We have chosen to consider what these papers say, and where they could lead, in respect to one of the most intractable problems with diabetes in New Zealand—the unfair burden of diabetes on Māori and Pacific peoples. This disproportionate burden has been reported for at least 30 years7 and Māori diabetes has been a national priority since at least 2001.8 Despite real efforts and some successes,9,10 even those who have contributed enormously will agree that the net effect remains incomplete and inadequate. We consider each paper in turn, recognising that we do not necessarily address the issues of central interest to the authors.
6	Are there disparities in care in people with diabetes? A review of care provided in general practice	Lawrenson R, Gibbons V, Joshy G, Choi P **J Prim Health Care**. 2009;1(3):177-83	 2009 Lawrenson et al - Are there dispari https://pubmed.ncbi.nlm.nih.gov/20690380/	The overall prevalence of diabetes in patients aged 20 years or older was 1221/26 096 (4.7%). Eighty percent had attended for a 'Get Checked' annual review in the last 12 months. After adjusting for age, we found that Maori, males and those diagnosed more than five years ago were at increased risk of having unsatisfactory glycaemic control. Maori or Asian patients and women appeared less likely to have accessed retinal screening in the last two years.
Related Data and Articles				
7	MOH Diabetes figures Māori/non Māori	https://www.health.govt.nz/our-work/populations/maori-health/tatau-kahukura-maori-health-statistics/nga-mana-hauora-tutohu-health-status-indicators/diabetes		
8	MOH Data and resources - background	https://www.health.govt.nz/our-work/populations/maori-health/wai-2575-health-services-and-outcomes-kaupapa-inquiry/wai-2575-maori-health-trends-report-data-and-resources		
9	Access Equity articles and research	 Journal articles and research - access eq		

Analysis of whether PHARMAC could and should include ethnicity as an access criterion for type 2 diabetes medicines
(whether any targeting of type 2 diabetes treatments to certain ethnicities falls within the scope of the affirmative action measures under the NZ Bill of Rights)

Setting

The below analysis relates to a proposal to fund specific SGLT 2 inhibitors and GLP-1 agonists for patients with type 2 diabetes (T2DM). This proposal includes having an ethnicity access criterion specific to need, substituting for current 5-year cardiovascular risk or diabetic kidney disease clinical criteria

Access criteria within the proposal presume a hybrid pro-equity approach, which states the SA specifically as follows; ie where access relaxes the 5 year cardiovascular risk assessment or diabetic kidney disease (DKD) component for Māori and Pacific people, but otherwise retain the other criteria as ethnicity-indifferent/agnostic:

> 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 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 being diagnosed with type 2 diabetes during childhood or as a young adult; or
> 2 5 Patient has diabetic kidney disease**; and
> 3 Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the regular use of at least one blood-glucose lowering agent (e.g. metformin, vildagliptin or insulin) for at least 3 months; and
> 4. Treatment will not be used in combination with a funded [GLP-1 agonist/SGLT-2 inhibitor] (deleted as appropriate).
>
> Note:
> Criteria 2.1 – 2.5 describe 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)

Not analysed at this stage is an alternative option of having broader ethnicity access criteria, which substitute for all other entry criteria aside from patients having type 2 diabetes. This option would have been wider for Māori/Pacific people with T2DM, in which SA criteria would simply permit anyone with T2DM who is Māori/Pacfic to gain access. This alternative would have been in line with some consultation feedback, and may be revisited in future.

Background/context Human Rights Commission, and Legal advice to PHARMAC

Human Rights Commission

According to the Human Rights Commission (https://www.hrc.co.nz/enquiries-and-complaints/faqs/positive actions achieve equality/), both the Human Rights Act and the

New Zealand Bill of Rights Act recognise that, to overcome discrimination, positive actions may be needed to enable particular groups to achieve equal outcomes with other groups in our society, as 'special measures' or 'affirmative action'. The HRC states these are not discriminatory if they assist people in certain groups to achieve equality; but any special measure must be based on information that shows that the present position is unequal.

The HRC states eight guidelines:

1. Measures to ensure equality contribute to but can never be a substitute for programmes for all New Zealanders designed to ensure access to decent work, healthy affordable housing and effective delivery of health, education and other services.
2. Measures to ensure equality are not only permitted but at times required, to ensure equality for disadvantaged groups.
3 The measure must be necessary to address disadvantage or ensure equality with other members of the community for groups against whom it is unlawful to discriminate.
4. The measure must be carried out in good faith.
5 The measure must be tailored to reduce the actual disadvantage of the group it is aimed at
6. The impact of the measure on those to whom it does not apply should be considered.
7. Measures to ensure equality should be proportional to the degree of under-representation or disadvantage
8. Measures to ensure equality should be temporary.

Further detail is in the HRC's 'Guidelines on Measures to Ensure Equality'

03-Mar-2010_16-12-18_Special_Measure

For more information on the role of special public policy measures addressing ethnic inequity, see Callister P Special measures to reduce ethnic disadvantage in New Zealand: an examination of their role. Wellington: VUW Institute of Policy Studies, 2007.

Legal advice to PHARMAC

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The fit of targeted approaches within wider policy frameworks

Providing legal principles are met, using ethnicity as a basis for providing medicines is compatible with PHARMAC's internal and external operating environments:

- **Wider health system:** The Ministry of Health's equity definition recognises different people with different levels of advantage require different approaches and resources to get equitable health outcomes[1]. Additionally, District Health Boards and Primary Health Organisations consistently positively discriminate access to services by ethnicity and deprivation quintile, as well as clinical criteria

[1] https://www.health.govt.nz/about-ministry/what-we-do/work-programme-2019-20/achieving-equity

- **New Zealand Human Rights Commission:** The HRC has stated "Measures to ensure equality are not only permitted but at times required. They are not discriminatory if they assist people in certain groups to achieve equality[2]."
- **New Zealand Public Health and Disability Act 2000:** This envisages the use of affirmative action measures applied at the population level where those measures are permitted under the general law[3]
- **New Zealand Bill of Rights Act 1990:** This recognises that affirmative actions are not discriminatory if they assist people in certain groups to achieve equality[4]

Analysis under the six Legal criteria

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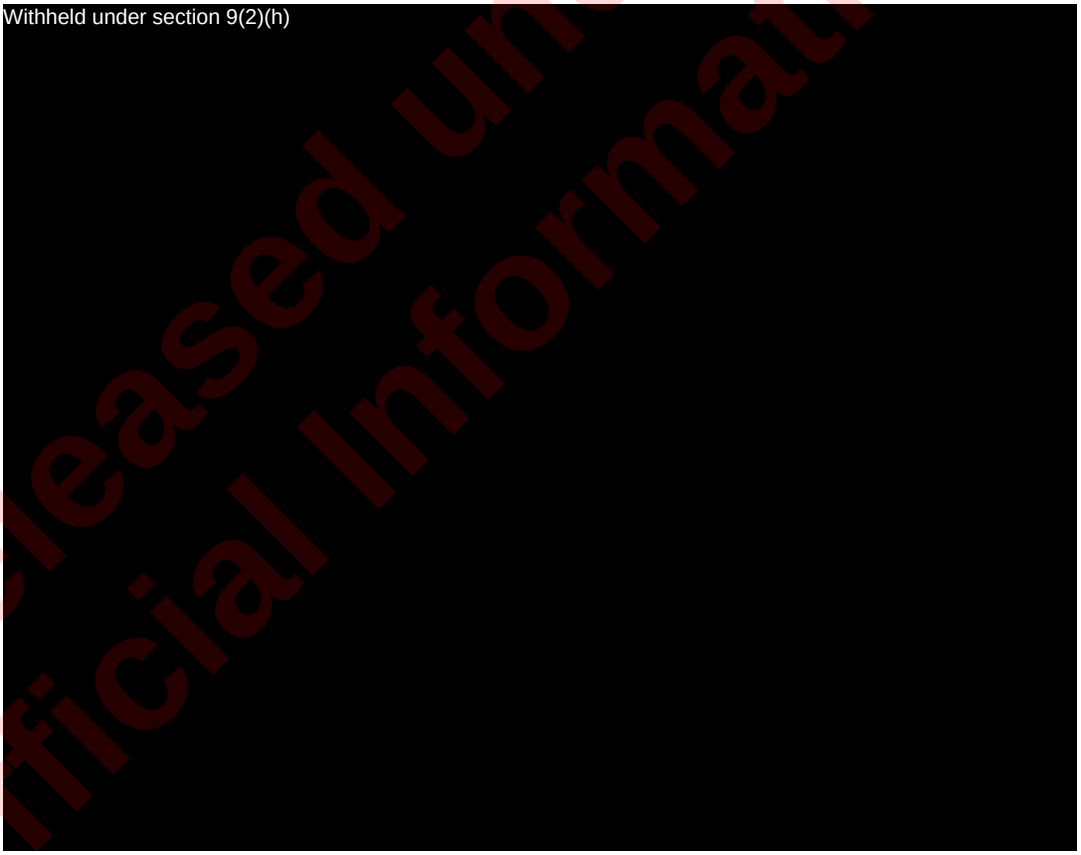

[2] https://www.hrc.co.nz/enquiries-and-complaints/faqs/positive-actions-achieve-equality/

[3] http://www.legislation.govt.nz/act/public/2000/0091/latest/DLM80057.html

[4] http://www justice.govt nz/assets/Documents/Publications/Guidelines-to-Bill-of-Rights-Act pdf

Under and using the six elements, having **the proposed ethnicity based access criteria** for specific SGLT 2 inhibitors and GLP 1 agonists for T2DM **does appear to meet the affirmative action measures** under the NZ Bill of Rights, as follows:

1) *Including ethnicity as an access criterion does so in order to improve health outcomes for a disadvantaged group, particularly where it can be shown that the group is disadvantaged because of discriminatory treatment in the health system*

There is widespread evidence that Māori and Pacific people are very disproportionately impacted by type 2 diabetes,[5] with a disease burden at least 6 7 times that of non-Māori/non-Pacific,[6] and have the capacity to benefit from these treatments. In addition, there is clear evidence that both population groups have been discriminated by the health system, which has been well documented.[7],[8],[9],[10]

More detail/supplementary information is available here.

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Of the 195,00 people dispensed medicines for type 2 diabetes (metformin and/or sulphonylureas +/ insulin; in 2018/19 data), Māori and Pacific people have age standardised dispensing rates nearly three time that of non Māori/non Pacific people. However, the commensurate recalculated >6 7 times disease burden in Māori and Pacific for type 2 diabetes means that their DALY adjusted dispensing rates are <54 61% less than they should be (were they to have the same dispensing rates, adjusted for disease burden, as occur in non-Māori/non-Pacific people).

[5] Yu D, Zhao Z, Osuagwu UL, Pickering K, Baker J, Cutfield R, Orr-Walker BJ, Cai Y, Simmons D. Ethnic differences in mortality and hospital admission rates between Māori, Pacific, and European New Zealanders with type 2 diabetes between 1994 and 2018: a retrospective, population-based, longitudinal cohort study Lancet Glob Health 2020:S2214-109X(20)30412-5

[6] Calculated from the 3.71 relative risk (RR) Maori:nonMaori all diabetes DALY loss in 2006 in the NZBDS (Ministry of Health Health loss in New Zealand: A report from the New Zealand Burden Of Diseases, Injuries And Risk Factors Study, 2006–2016 Wellington: Ministry of Health, 2013.), adjusted with 1.10 inflator for M:nM RR T2DM vs all diabetes (where T1DM assumed equal disease burden across ethnic group) x 1.52 inflator for MP RR vs M RR (where Pacific people dilute the Māori:nM effect by including in nM) +/- x 1.78 inflator for MP RR vs M RR, when P>M for T2DM hospitalisations; overall adjusted RR 6.2-7.3.

Note these RRs may be further underestimates still, as the source NZ Burden of Disease Study data provided age-standardised relative risks based on the WHO world standard population, which understates gaps when compared with using a younger age standard population – ie the need to use of the age structure of the groups experiencing the greatest disadvantage (see Robson B, Purdie G, Cram F, Simmonds S Age standardisation–an indigenous standard? Emerg Themes Epidemiol 2007; 4(1):3)

[7] Waitangi Tribunal (Te Rōpū Whakamana i te Tiriti o Waitangi) Hauora: Report on Stage One of the Health Services and Outcomes Kaupapa Inquiry. WAI 2575. Wellington: Department of Justice, 2019 https://waitangitribunal.govt nz/inquiries/kaupapa-inquiries/health-services-and-outcomes-inquiry/

Chin MH, King PT, Jones RG, Jones B, Ameratunga SN, Muramatsu N, Derrett S Lessons for achieving health equity comparing Aotearoa/New Zealand and the United States Health Policy 2018;122(8):837-53

Harris R, Tobias M, Jeffreys M, Waldegrave K, Karlsen S, Nazroo J Effects of self-reported racial discrimination and deprivation on Māori health and inequalities in New Zealand: cross-sectional study. Lancet. 2006;367(9527):2005-9.

Harris RB, Stanley J, Cormack DM Racism and health in New Zealand: Prevalence over time and associations between recent experience of racism and health and wellbeing measures using national survey data. PLoS One. 2018;13(5):e0196476.

[8] https://www health govt nz/publication/ola-manuia-pacific-health-and-wellbeing-action-plan-2020-2025

https://www health govt nz/publication/tupu-ola-moui-pacific-health-chart-book-2012

https://www.moh.govt.nz/notebook/nbbooks.nsf/0/A31842D91480064FCC256A55007A980A/$file/PrioritiesForMaoriandPacificHealth.pdf

https://www.nzcphm.org.nz/media/87942/2019_12_05_pacific_peoples_health_policy_statement.pdf

[9] Rata E, Zubaran C. Ethnic Classification in the New Zealand Health Care System. J Med Philos. 2016;41(2):192-209.

[10] Jansen RM, Sundborn G, Cutfield R, Yu D, Simmons D. Ethnic inequity in diabetes outcomes-inaction in the face of need. N Z Med J. 2020;133(1525):8-10.

FYR	2019
Diabetes_Type	Type2
T2D Treatment	T2D meds

no. patients on Rx

Sum of no.	EG4		
Life_Stage_Band	MP	nMnP	Total
Youth (15-24)	648	426	1074
Young adult (25-44)	8717	9080	17797
Middle aged adult (45-64)	32333	49807	82140
Older adult (65-74)	14073	38508	52581
Very old (75+)	6470	35067	41537
Total	**62241**	**132888**	**195129**

MP = Māori or Pacific people; nMnP = non-Māori/non-Pacific

pts on Rx rates:1000 population

Life_Stage_Band	MP	nMnP
Youth (15-24)	3.2	0.9
Young adult (25-44)	29.9	8.9
Middle aged adult (45-64	145.6	49.0
Older adult (65-74)	268.2	96.0
Very old (75+)	262.8	114.9
(crude rate)	78.2	41.6
age-standardised rate	*59.8*	*20.9*

2020-12
Maori&Pacific DALY-a

FYR	2019
Diabetes_Type	Type2
T2D Treatment	T2D meds

Rate ratios (RR) MP vs nMnP

(adjusted for T2DM vs all diabetes (T1DM removed) and PI, assumes PI = M rates;

+/- adjusted for higher T2DM hospitalisation rate for PI vs M)

RRs for patients on Rx:

Life_Stage_Band	MP	nMnP
Youth (15-24)	3.33	1.00
Young adult (25-44)	3.36	1.00
Middle aged adult (45-64)	2.97	1.00
Older adult (65-74)	2.79	1.00
Very old (75+)	2.29	1.00
(crude rate ratio)	1.88	1.00
age-standardised RR	*2.87*	*1.00*

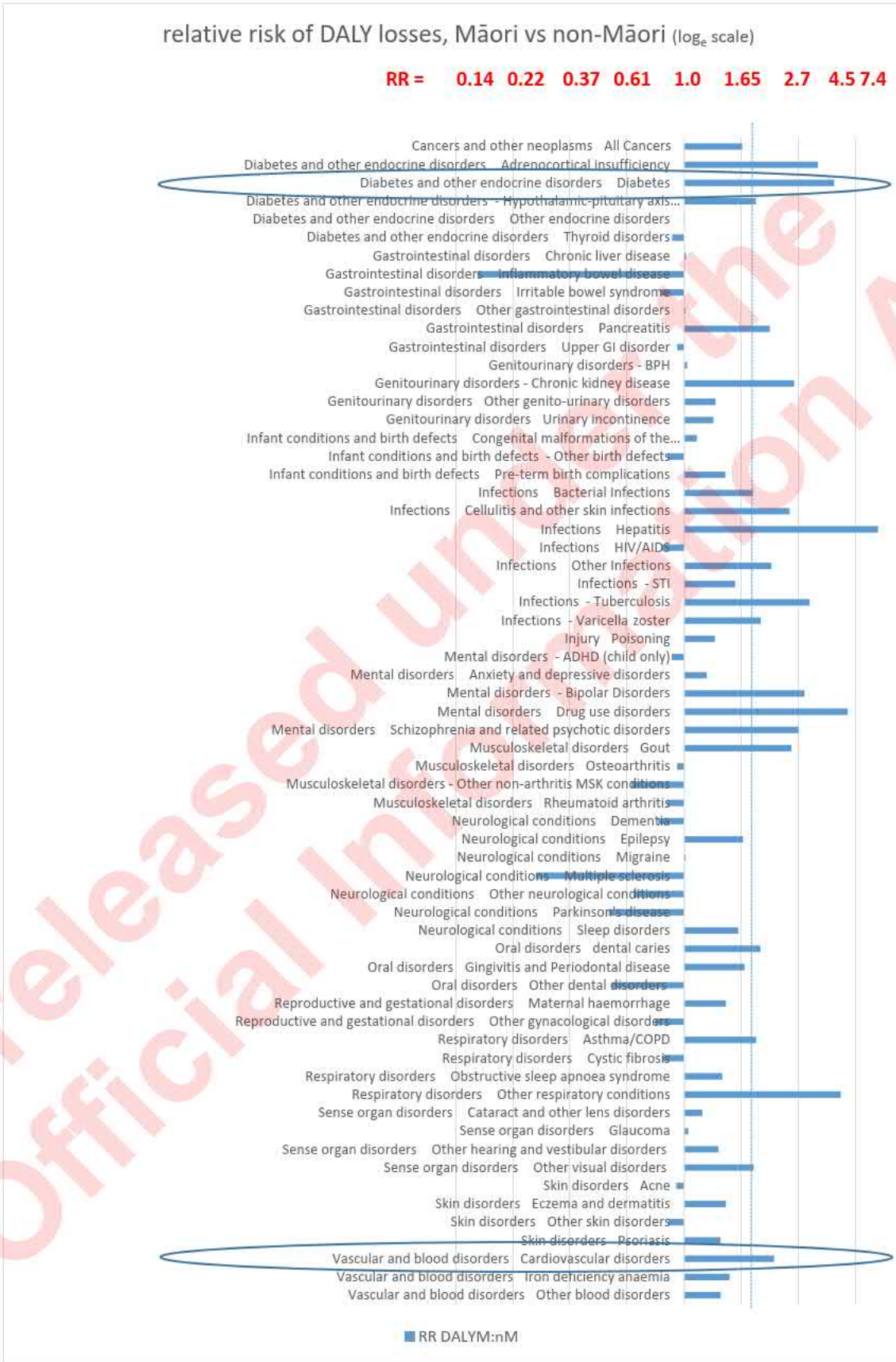
DALYL RRs, then DALY-adjusted RRx for patients on Rx:

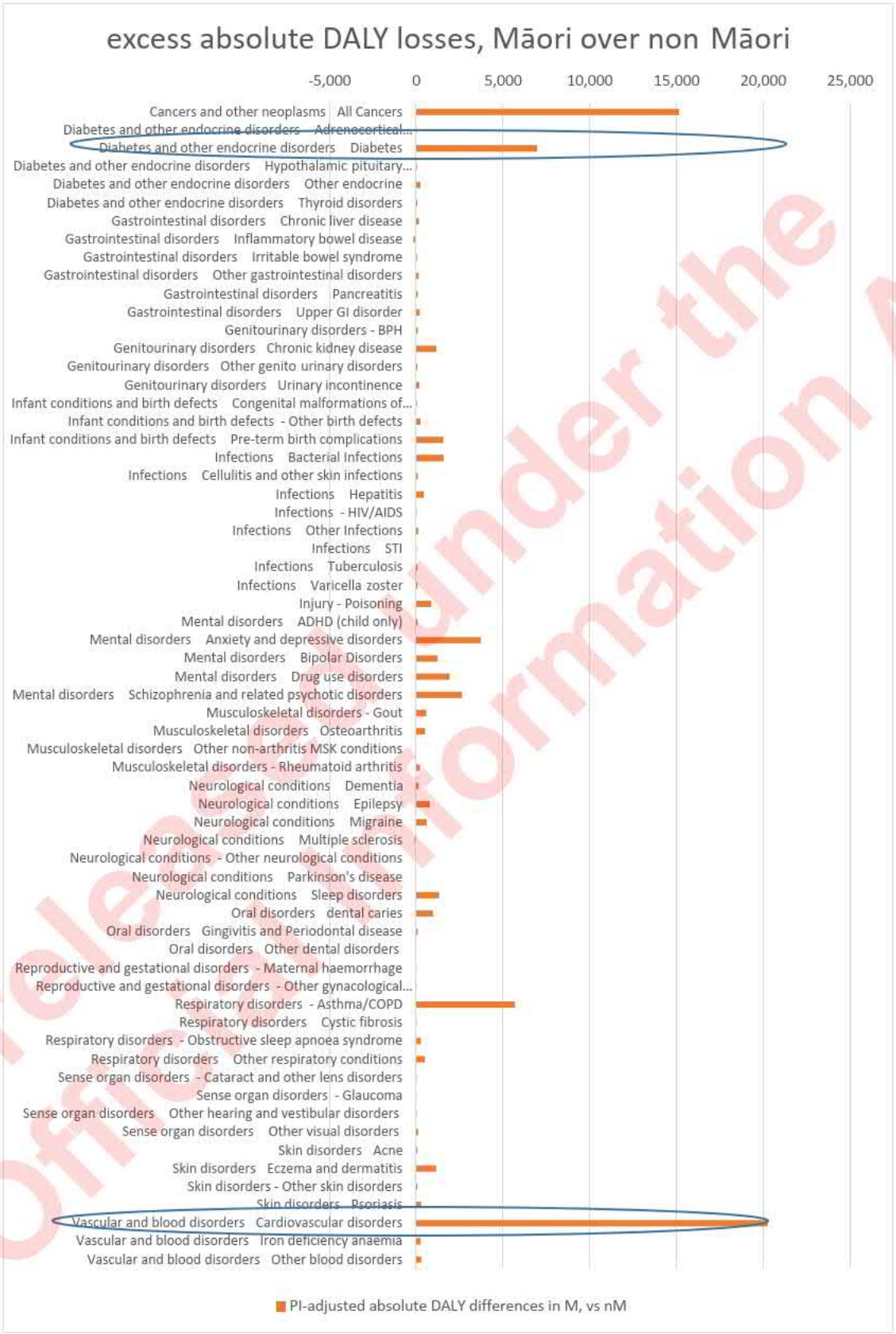
(all diabetes as-DALYL M:nM)	3.7	
T2DM as-DALYL MP:nMnP	6.2	(T2DM; as-DALYL M:nM, adjusted for PI prevalence (assumes M=PI RR))
Age-DALY-adjusted Rx rate ratio MP:nMn	0.4617	
Rx % deficit (-), excess (+)	-53.8%	
adjusted as-DALYL M,P:nMnP	7.3	(+ further adjusted for higher T2DM hospitalisation rate for PI vs M)
Age-DALY-adjusted Rx rate ratio M,P:nMr	0.395	
Rx % deficit (-), excess (+)	-60.5%	

By way of context, relative excess disease burden between Māori/Pacific people and non Māori/non-Pacific in type 2 diabetes is possibly exceeded only by viral hepatitis across all disease burden categories (surpassing arteriosclerotic cardiovascular disease and combined cancers; although these have numerically greater excess DALY losses in Māori/Pacific people):[11]

2Copy of Absolute diffs and RRx from DA

[11] source data from: Auckland UniServices. Variation in medicines use by ethnicity: a comparison between 2006/7 and 2012/13. Final Report Prepared for PHARMAC. Auckland: University of Auckland, 2018, and its appended spreadsheets at https://pharmac.govt.nz/te-tiriti-o-waitangi/programmes-to-support-maori-health/maori-uptake-of-medicines/





2) *There is a real prospect that the inclusion of ethnicity in access criteria will address the disadvantage that is identified*

PHARMAC has received clear and persuasive consultation feedback from recognised experts, that the inclusion of an ethnicity criteria has the genuine potential to address the disadvantage.

The gap between medicines need and uptake by ethnic groups persists, despite many years of discussion in the Health Sector, with good evidence that the apparent deficit in disease burden adjusted, age standardised dispensing for diabetes and renal disease does not appear to be closing [12],[13],[14] This evidence suggests that the deficit is equally between access and persistence. As a result it is reasonable to conclude that activity to both increase access and maintain persistence in those who are initiated on treatment is required PHARMAC has received clear consultation feedback and advice that the inclusion of an ethnicity criteria may address the disadvantage.

We also received advice from recognised experts that Māori and Pacific people do not have equitable access to the clinical testing that would enable funded access under the original proposed criteria The inclusion of the ethnicity component in the criteria can be expected to have the effect of partially removing this barrier and hence addressing the clear disparities.

3) *Including ethnicity as an access criterion does consider whether there may be reasonable (and similarly effective) alternative solutions that do not involve making distinctions on the basis of ethnicity*

PHARMAC staff had originally crafted the Special Authority criteria with a view to being pro equity using purely clinical criteria. Feedback received from the recognised experts during consultation argued that these criteria were inadequate on the basis that Māori and Pacific people with type 2 diabetes have demonstrated differential cardiovascular and renal risk that cannot be fully captured in any other way Furthermore, staff received persuasive feedback from recognised experts that Māori and Pacific people do not have equitable access to the clinical testing that would enable funded access under the original proposed criteria.

Staff considered the option of open listing these medicines, however this would not be possible within the available budget for pharmaceuticals. Furthermore, recent data suggests that open listing in itself is ineffective in addressing inequities in access to medicines [15]

Hence, to date, staff cannot identify any other means in the Pharmaceutical Schedule for redressing entrenched access inequities, and where evidence is lacking from other

[12] Metcalfe S, Beyene K, Urlich J, Jones R, Proffitt C, Harrison J, Andrews Ā. Te Wero tonu—the challenge continues: Māori access to medicines 2006/07-2012/13 update. N Z Med J. 2018;131:27-47.

[13] Auckland UniServices. Variation in medicines use by ethnicity: a comparison between 2006/7 and 2012/13. Final Report. Prepared for PHARMAC. Auckland: University of Auckland, 2018. https://pharmac.govt.nz/te-tiriti-o-waitangi/programmes-to-support-maori-health/maori-uptake-of-medicines/

[14] Appendices and data Appendices H and I to: Auckland UniServices. Variation in medicines use by ethnicity: a comparison between 2006/7 and 2012/13 Final Report Prepared for PHARMAC Auckland: University of Auckland, 2018. https://pharmac.govt nz/te-tiriti-o-waitangi/programmes-to-support-maori-health/maori-uptake-of-medicines/

[15] Chepulis L, Mayo C, Morison B, Keenan R, Lao C, Paul R, Lawrenson R Metformin adherence in patients with type 2 diabetes and its association with glycated haemoglobin levels J Prim Health Care 2020 (published online 5 November 2020)

programmes of sustained improvements that are rapid, sufficiently large and sufficiently timely to rapidly redress inequities.

This approach recognises SA criteria are but one of many parts of a system that will be required to redress funded access inequities; alone as an action it is insufficient, but it is still necessary (where if each component was excluded because in itself it was insufficient, there would be no components; each plays a part and as such is necessary)

4) *Including ethnicity as an access criterion does consider whether any proposed use of ethnicity as a criterion is wider than necessary and whether, if ethnicity is a direct proxy for other causative factors (such as socioeconomic status), it may be more effective to address those factors directly*

This issue has been considered through the drafting of the SA criteria In this case the inclusion of ethnicity is a proxy for those people who have been the subject of complex systemic inequities and therefore are at a higher risk of complications from type 2 diabetes This is independent of clinical variables that could instead be included We do not consider that the use of a particular gene or socioeconomic status would be possible, practical, or appropriate in this particular scenario; we have been unable to identify any other factor which could be used to identify this group that could be workably applied as a criterion in clinical practice.

The risk of inappropriate use (ie by M/PP patients with T2DM accessing treatments needlessly) is considered very low, as the criteria as written require first line inadequate treatment effectiveness or intolerance already, and only relax (in a minor way) the absolute 5 year cardiovascular risk/DKD component.

Further, the inclusion of the ethnicity criterion is not as a proxy for other factors, rather it is a predictor of poorer disease outcomes. Māori and Pacific ethnicity is included as part of the 5-year CV risk calculations[16] (as are other ethnicities). However, this is the point of including a separate ethnicity component in the five cardiovascular/renal risk criteria 2 1 2 5 that the 5-year risk calculations do not account for Māori and Pacific people having poorer access to health services, as well-evidenced with the known ethnic inequities in needs (disease burden) adjusted metformin access [17],[18],[19]

Regarding whether the presence of socioeconomic status (or indeed a particular gene) could be addressed directly, there is not one known specific gene that could be targeted, and socioeconomic factors are outside of the scope of what PHARMAC could meaningfully address.

(Note that in terms any epidemiological consideration of genetic factors, such factors may be overplayed This is where particular genes are rarely a consideration the

[16] Pylypchuk R, Wells S, Kerr A, Poppe K, Riddell T, Harwood M, Exeter D, Mehta S, Grey C, Wu BP, Metcalf P, Warren J, Harrison J, Marshall R, Jackson R. Cardiovascular disease risk prediction equations in 400 000 primary care patients in New Zealand: a derivation and validation study. Lancet. 2018;391(10133):1897-907.

[17] Metcalfe S, Beyene K, Urlich J, Jones R, Proffitt C, Harrison J, Andrews Ā. Te Wero tonu—the challenge continues: Māori access to medicines 2006/07-2012/13 update. N Z Med J. 2018;131:27-47.

[18] Auckland UniServices. Variation in medicines use by ethnicity: a comparison between 2006/7 and 2012/13. Final Report. Prepared for PHARMAC. Auckland: University of Auckland, 2018. https://pharmac.govt.nz/te-tiriti-o-waitangi/programmes-to-support-maori-health/maori-uptake-of-medicines/

[19] Appendices and data Appendices H and I to: Auckland UniServices Variation in medicines use by ethnicity: a comparison between 2006/7 and 2012/13 Final Report Prepared for PHARMAC Auckland: University of Auckland, 2018. https://pharmac.govt nz/te-tiriti-o-waitangi/programmes-to-support-maori-health/maori-uptake-of-medicines/

evidence, when looked for (rarely nowadays), is usually too underpowered to detect a statistically robust difference between ethnic groups in New Zealand, where the absence of evidence is not evidence of absence[20],[21]), and in the context of the much greater impacts of socioeconomic deprivation, colonisation, racism etc)

5) *Including ethnicity as an access criterion does consider the position of those not able to access the pharmaceutical(s) in question, as well as any issues of over- or under-inclusion (where people who do not need a measure benefit simply because they belong to the targeted group, while others who may need it are denied the benefit because they belong to a group considered not to be disadvantaged)*

The SA criteria have been drafted to ensure all those (regardless of ethnicity) who are most likely to benefit can access the pharmaceuticals. Broadening any further without specifically naming ethnicity would widen access to a group who are unlikely to benefit, with an opportunity cost to the CPB

We can reasonably determine that Māori and Pacific would fall into the group most likely to benefit, but we cannot clearly define these groups in any other way.

The issue of over inclusion (of Māori and Pacific people with cardiovascular risk apart from 15%+ 5-year cardiovascular risk, of diabetic kidney disease, or young diagnosis of T2DM where people who do not need a measure benefit simply because they belong to the targeted group) has been considered, but rather than disadvantage certain groups, the SA criteria would better target the pharmaceuticals in question to those with the greatest need.

The position of those not able to access the pharmaceutical(s) in question, with under-inclusion (where people who may need it are denied the benefit because they belong to a group considered not to be disadvantaged) has been addressed. The criteria as pertains to non-Māori/non-Pacific people will meet the needs of all those with T2DM with sufficiently severe treatment resistant disease to warrant the new treatments cost effectively (ie their health gains will be ample) In particular, criterion 2 4 ”Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult” applies to the (proportionately fewer) non Māori/non Pacific young people at high lifetime risk who do not already meet other cardiovascular/renal risk criteria 2.2 2.3 or 2.5 (as would Māori/ or Pacific people). Likewise, criterion 2.5 “diabetic kidney disease” covers those non-Māori/non-Pacific with diabetic kidney disease not covered by criterion 2 3 etc

The other group who might need specific mention (at risk of being denied access) under ethnicity-based criteria is South Asian ethnicities. However, those who would benefit from that group (and other groups not considered to be disadvantaged) would be able to access via the standard criteria, where:

- The available evidence in relation to medicine access by South Asian/Indian ethnicity is from the Auckland region, where Indian people have access to diabetes medicines and cardiovascular triple therapy at rates similar to NZ

[20] Altman DG, Bland JM Absence of evidence is not evidence of absence BMJ 1995;311(7003):485 https://www.bmj.com/content/311/7003/485.long

[21] https://www evidentlycochrane.net/teapots-and-unicorns-absence-of-evidence-is-not-evidence-of-absence/

Europeans and access rates much higher than Māori and Pacific peoples [22] This suggests that, in contrast to Māori and Pacific people, systemic barriers and outcomes disparities do not appear to be as significant for South Asian/Indian people, and they are able to access medicines at higher rates for CVD and diabetes. At this stage it would appear, under the proposed criteria, they would get good access, as people who do not meet the proposed ethnicity criterion but who would benefit most from treatment, who would be captured through the other criteria used to define those at high risk of cardiovascular or renal complications of diabetes.

- Indian ethnicity is also included as part of the 5 year CV risk calculations[23] (as is Māori and Pacific ethnicities, albeit the calculations do not account for their poorer access to health services).

6) *PHARMAC will It regularly monitor and evaluate the effectiveness of using ethnicity as an access criterion*

PHARMAC staff have developed methodology for measuring medicines access equity specific to type 2 diabetes. If approved, this methodology would be applied to the new medicines with a view to influencing equitable access drivers across the health sector.

Furthermore, staff are working to develop methodology for timely monitoring of SA applications to monitor uptake with an equity lens In the case of these medicines, the simple proportion of approved SA applications that apply under criterion 2 1 ("2 1 Patient is Māori or any Pacific ethnicity") will be simple yet highly relevant. This is where 2.1 is the first of any five subcriteria in criterion 2 defining patients at high risk of cardiovascular or renal complications of diabetes, where meeting criterion 2 is necessary for access.

Should this proposal be approved, PHARMAC would look to publish this data in a way that would enable the sector to understand where access could be improved.

If the proposed criterion 2.1 was not being utilised, and aspirations for medicines access equity (based on a need-adjusted uptake) were being met already under criteria 2.2 to 2 5, there might be a case for considering the removal of this criterion at a future point in time, subject to public consultation.

[22] Wing Cheuk Chan. Diabetes care in the context of SGLT-2 inhibitor and GLP-1 agonists: How many people in Auckland metro are meeting clinical criteria in the context of multi-morbidities? Population Health Team, Counties Manukau District Health Board, 21 November 2020. Slides 15-17, 20-24

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[23] Pylypchuk R, Wells S, Kerr A, Poppe K, Riddell T, Harwood M, Exeter D, Mehta S, Grey C, Wu BP, Metcalf P, Warren J, Harrison J, Marshall R, Jackson R Cardiovascular disease risk prediction equations in 400 000 primary care patients in New Zealand: a derivation and validation study. Lancet 2018;391(10133):1897-907

Supplementary information to: Analysis of whether PHARMAC could and should include ethnicity as an access criterion for type 2 diabetes medicines

Medicines access inequities

Among eligible people in New Zealand, significant negative health disparities[1] that are unfair and avoidable (ie. inequities[2,3,11]) exist, with Māori and Pacific peoples in particular experiencing poorer health outcomes than non-Māori/non-Pacific populations.

Inequalities in health risks, disease rates, medication access and usage, and health outcomes between ethnic groups are well-described.[9] While some of these inequalities are due in part to population characteristics and are unavoidable, they are also inequitable when associated with social, economic or health-system related factors that are unfair and avoidable.[1-3,10]

The evidence of inequities in health outcomes between ethnic groups in New Zealand is clear.[12-16] Eg.

- According to recent data from Statistics NZ, life expectancy at birth in 2013 was 73.0 years for Māori males and 77.1 years for Māori females, compared with 80.3 years for non-Māori males and 83.9 years for non-Māori females.[12]
- The Māori infant mortality rate was also higher than the national average.[13]
- Exposure to health risks and morbidity are generally higher among Māori than non-Māori, reflecting inequities in the social determinants of health.
- Māori have higher rates of cardiovascular disorders, asthma, diabetes, raised blood pressure, lung cancer, substance use disorders, suicide and mental health problems than non-Māori.[14] In the most recent New Zealand Burden of Disease (NZBD) study, for cardiovascular disorders and diabetes, health loss for Māori was 2.5 times higher than for the non-Māori, after accounting for age structure and population size differences.[14]

These inequities represent significant, avoidable morbidity and mortality for Māori. For example, had Māori experienced similar mortality and morbidity rates to non-Māori for diseases occurring in 2006, 67,000 fewer years of healthy life would have been lost across the whole population in that year.[14] Eliminating inequity in health outcomes would have reduced the burden of disease in the whole population by 7% and in the Māori population by 42%.[14]

Excess disease burden in Māori compared with non-Māori has been the leading cause of health loss in New Zealand, more than any disease or risk factor.[17] Analysis on the New Zealand College of Public Health Medicine's website at https://www.nzcphm.org.nz/media/95762/2006_daly_losses.pdf[17] depicts how, in 2006 (the only year that such pan-category burden of disease analysis has been available for New Zealand), of all combined categories integrating burden by disease, risk factors and crude inequity (Māori vs non Māori), including double counting (totalling 1.5 million DALYs lost, where true disease burden across disease and injury alone was 955,230 DALYL, of which risk factors contributed to 417,753 DALYL), excess disease burden in Maori vs non-Maori had the highest DALYs lost of all disease and risk factors, losing some 118,954 DALYs.

Inequities in health care and outcomes borne by Māori and other New Zealanders, including medicines access, are unacceptable. Health inequities are inconsistent with principles of social justice and human rights, including indigenous rights as reaffirmed by te Tiriti o Waitangi[26] and the United Nations Declaration on the Rights of Indigenous People (UNDRIP).[27-29] This is where the lack of improvement in top-line medicines access for Māori signals that the broader health system[endnote A] as a

whole has yet to take all the "necessary steps" for indigenous people to attain equal standards of health (as per UNDRIP article 24(2),[27,28] supported by New Zealand[29]) (see endnote B).

Human life and potential is wasted when not everyone gets the healthcare they are entitled to—when every person in New Zealand should have the same access to the funded medicines they need; as a society, we lose opportunities when people don't get to live, thrive and participate.[30]

The causes of inequities are complex, and solutions lie beyond simply the funding of medicines or simply the health system. There are likely barriers to equity at multiple levels**Error! Reference source not found.**,[24] including:

- patient/population factors as access barriers to health care (including accessing appointments, delayed access), related to costs, transport, family structure, expectations, beliefs, etc;
- health system factors with structural barriers such as how care is organised (eg. accessing appointments, wait times, after hours advice and access, completing referrals); and
- health professional factors leading to differential treatment, with inability of providers and health systems to address all groups' needs equitably (institutional and professional bias, cultural competency,[32] health literacy involving health professionals (ie. beyond patients/whānau),[33] knowledge and skills, adherence, etc.)

—all in the context of inequities in wider underlying structural and systems[34] (including institutional and professional bias), social and economic determinants of health.[10,9-11,15,**Error! Reference source not found.**,24,32,34-47]

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Endnotes

A. "Broader health system" here refers to all sectors integral to the wider social, economic and environmental determinants of health[Error! Reference source not found.], eg Health, Education, Housing, etc. Wider determinants of health are the factors outside of the health system that contribute to people's health and wellbeing, including housing, income, education, and employment.[Error! Reference source not found.]

B. Under the United Nations Declaration on the Rights of Indigenous People (UNDRIP), article 24 states[28]

> "1. Indigenous peoples have the right to… access, without any discrimination, to all social and health services.
>
> 2. Indigenous individuals have an equal right to the enjoyment of the highest attainable standard of physical and mental health. States shall take the necessary steps with a view to achieving progressively the full realization of this right."

Te Whaioranga 2013-2023, PHARMAC's Māori Responsiveness Strategy,[7] notes that te Tiriti o Waitangi is complemented by the Declaration on the Rights of Indigenous Peoples adopted by the United Nations General Assembly in 2007[27,28] and supported by the New Zealand Government in April 2010.[29] Te Whaioranga also comments the Declaration provides international support to te Tiriti on responsible government, tino rangatiratanga and equal rights for all, including for health (articles 21, 24 and 43 of the Declaration[28]).

C. Cultural safety vs. cultural competence: Both cultural competence and safety relate to the relationship between the helper and the person being helped. However, cultural safety centres on the experiences of the patient, whereas cultural competence focuses on the capacity of the health worker to improve health status by integrating culture into the clinical context.[56]

Inequities in medication access and usage, health outcomes, disease or health risks between ethnic groups have been extensively documented.[1,2] While some forms of these inequities are attributable to differences in population characteristics and may not be avoidable, the others are associated with social, economic or health-system related factors and often are unfair and avoidable.[3] The latter form of inequity is the focus of this research. Equity is an ethical concept, and inequities cannot be measured using standard quantitative tools,[4] but an analysis of the fairness/unfairness and avoidability/unavoidability of any difference can expose inequities.

There is clear evidence of inequities in health outcomes between ethnic groups in Aotearoa/New Zealand (NZ). According to recent data from Statistics NZ, for example, life expectancy at birth in 2013 was 73.0 years for Māori males and 77.1 years for Māori females, compared with 80.3 years for non-Māori males and 83.9 years for non-Māori females.[5] The Māori infant mortality rate was also higher than

the national average.[6] Exposure to health risks and morbidity are generally higher among Māori than non-Māori, reflecting inequities in the social determinants of health. Māori have higher rates of cardiovascular disorders, asthma, diabetes, hypertension, lung cancer, substance use disorders, suicide and mental health problems than non-Māori.[7] In the most recent New Zealand Burden of Disease (NZBD) study, for cardiovascular disorders and diabetes, health loss for Māori was 2.5 times higher than for the non-Māori, after accounting for age structure and population size differences.[7] These inequities represent significant, avoidable morbidity and mortality for Māori. For example, had Māori experienced similar mortality and morbidity rates to non-Māori for diseases occurring in 2006, 67,000 fewer years of healthy life would have been lost across the whole population in that year.[7] Eliminating inequity in health outcomes would have reduced the burden of disease in the whole population by 7% and in the Māori population by 42%.[7] These health inequities violate the principles of social justice and represent a breach of human rights, including indigenous rights as reaffirmed by the Treaty of Waitangi.[8]

Overall, causes of health inequities are complex, and some of them are beyond health care. A number of explanations have historically been proposed for observed ethnic differences in health outcomes, including differences in genetics and culture, lifestyle, access to and quality of health care, institutional racism and discrimination, and socioeconomic inequities.[9-12] Historically, genetic differences and unhealthy behaviours (such as high rates of smoking, alcohol use and fatty diet consumptions among ethnic minorities) have been dominant themes cited to explain health inequities in medical literature; however, these can only partially explain health inequities.[12] Instead, socioeconomic challenges faced by ethnic minorities are the major causes of health inequities and poorer health outcomes.[9,12,13]

Current understandings of ethnic health inequalities emphasise their complex, multifactorial aetiology, fundamentally driven by inequities in societal systems and structures.[13,14] It is therefore important to use a conceptual framework as the basis for understanding and addressing these inequities. One such framework, developed in the United States (US) to assist in the analysis and explanation of racial disparities in health, describes a pathway from basic causes to health outcomes.[15] The mechanisms by which ethnic inequities are created and maintained involve a wide range of factors operating at different levels. They include access to socioeconomic resources such as housing, education and employment, behavioural patterns and responses, and health system factors that result in inequities in access to and quality of health care. However, the critical feature of the framework is that these factors are all driven by the 'basic causes', which include political, legal, economic and cultural institutions – but also, importantly, racism. In Aotearoa/New Zealand, colonisation is a fundamental driver of poor health for Māori and racism is a root cause of ethnic inequities in health.[16]

By and large, health inequities are the product of poor housing conditions, high unemployment rate, lack of social support, less education, lower health literacy, lower income and poverty, and ethnic minorities are more likely to face all these challenges than the majority groups.[11,12] Additionally, ethnic minorities are over-represented in rural, remote and impoverished communities, and this could increase exposure to health risks.[12] Due to stereotyping and discrimination in health facilities, ethnic minorities may receive poorer quality health services, which in turn can lead to health inequities. For instance, studies have reported that many Māori perceive health facilities as unfriendly environments and reluctant to visit health care providers.[14,15] Apart from socioeconomic factors, longer waiting times to see a doctor, linguistic and cultural barriers to health care can play significant roles in the poor health status of ethnic minorities.[13]

The New Zealand health sector contributes to health inequities between Māori and non-Māori.[17,18] Health care disparities have many different causes, which can be broadly grouped into health system factors, health professional factors and patient or population factors.[19] One of the ways in which this can manifest is inequitable access to pharmaceuticals. [The update of the Māori medicines Gap analysis explores] differences in medicine access and use between ethnic groups, with particular emphasis on comparing Māori and non-Māori access to publicly funded community medicines.

Pharmaceuticals play a significant role in promoting and restoring the health of individuals and the public. Without adequate access to pharmaceuticals, individuals are at higher risk of morbidity and mortality. Ensuring equitable access to pharmaceuticals is therefore a global concern for health planners and agencies established to execute health policies. Significant progress has been made worldwide in the last several decades in improving equitable access and quality use of medicines (including NZ)[20]; however, despite many efforts problems with access have persisted for several reasons.

PHARMAC's role under te Tiriti o Waitangi

The Government's strategy for the medicines system seeks access and optimal use outcomes: that there is equity of access to medicines that are needed (and medicines resources are allocated in a manner that reduces inequality of outcome), and that medicines are used to their best effect (high-quality, safe and effective medicines are chosen, delivered and used in a way that ensures their potential to improve health and prevent illness is maximised, wastage is reduced and resources used more effectively). PHARMAC contributes to the wider New Zealand health sector of the Government outcome that "New Zealanders live longer, healthier, more independent lives". As a Government agency, PHARMAC also has a commitment to upholding the articles expressed through the principles of the Treaty of Waitangi.

PHARMAC's Māori Responsiveness Strategy – Te rautaki o Te Whaioranga – provides a longterm framework for ensuring that PHARMAC responds to the particular needs of Māori in relation to medicines.[26] The primary goal of Te Whaioranga is to ensure that Māori have access to subsidised medicines and use these medicines appropriately and safely.

Diabetes and renal disease, respiratory diseases (such as asthma, COPD and lung disease), cardiovascular disorders (eg. hypertension, thrombosis, dyslipidaemia, smoking cessation and metabolic syndrome), mental health, arthritis and gout and rheumatic fever are the main areas of focus for Māori health.[26] PHARMAC's goals for Māori health are in-line with He Korowai Oranga, that is, the overall Māori health strategy of the Ministry of Health.[27] Both strategies aim to close health gaps between

Māori and non-Māori populations through various health interventions, including improving medicine access and promoting optimal use of medicines.

Inequities in medication access and use

Inequities in medication access and use between ethnic and racial groups have been extensively researched.[28-35] Across studies, indigenous people and other disadvantaged ethnic minorities were less likely to access and adhere to prescribed medicines regimens than the 'reference population', which is usually the dominant culture. These studies reported ethnic and racial disparities across a range of medicines, including but not limited to, lipid lowering agents,[34] vaccines,[36] antidepressants,[31] asthma medicines,[30] antipsychotics,[37] statins[28,29] and antiretrovirals.[32] Additionally, disparity in access and/or adherence with prescribed medicines regimens were reported.[38] For example, Kharat et al, using a nationally

representative 2009 US medical expenditure panel survey data, found that the odds of receiving a prescription for inhaled corticosteroids among asthma patients were 43% lower for Hispanic adults compared with non-Hispanic White adults ($p<0.05$).[30] The authors expressed concern about sub-optimal treatment and higher rates of asthma exacerbation among Hispanics as the result of the observed inequality. In another US study, using a nationally representative sample, the odds of filling an antidepressant prescription were significantly lower for African Americans and Latinos than non-Hispanic Whites.[31] A Canadian study among 19,370 British Columbia urban residents also documented needs-adjusted inequalities in prescription medicines use between ethnic groups. In this study, Chinese were significantly less likely to fill prescriptions for statins, antibiotics, antihypertensive, respiratory medicines and antidepressants than Whites.[28]

In NZ, only a few studies have explored disparities in access to and persistence (i.e. failure to receive a second or subsequent dispensing) with prescribed medicines. A study that assessed financial barriers to accessing prescription medicines among 18,320 randomly sampled NZ adults reported that Māori and Pacific Peoples were more likely to defer obtaining a prescription medicine than NZ Europeans because of prescription charges.[39] Additionally, deferring obtaining medicines was significantly associated with poor self-reported health status, having two or more medical conditions and high stress.[39] A secondary analysis of national pharmaceutical claims data showed that asthma treatment for Māori and Pacific children was less likely to be escalated with severity of asthma, where they were more likely to be dispensed oral steroids to control asthma exacerbations than children of other ethnic groups, indicating poor asthma management among Māori and Pacific children.[40] On the contrary, using pharmacy dispensing data, Norris et al found that more statins were dispensed to Māori compared to non-Māori in the 45-54 age band, possibly due to a higher risk of cardiovascular diseases among Māori.[41] Metcalfe et al have presented a more detailed if preliminary analysis of disparities in community medicines access and persistence (or adherence) between ethnic groups in NZ.[33] Using national pharmaceutical claims data for the year 2006/07 and adjusting for age and disease burden differences between ethnic groups, the authors reported considerable differences in the number of dispensings than would have been expected based on the age/disease burden of Māori compared to non-Māori. The findings indicated that lower numbers of medicines dispensings happened for Māori across a number of medical conditions, such as infections, asthma prevention, cardiovascular diseases, diabetes, mental health and neurological conditions.

There is consistent evidence that Māori are at higher risk of cardiovascular disease than NZ European and that they are offered treatment at a lower rate and have lower persistence rates. Lower persistence rate should not necessarily be equated with traditional concepts of adherence. Persistence in this context also involves the health system providing services that are accessible and culturally safe, communicating the need for ongoing therapy, arranging follow-up appointments and keeping patients and communities engaged. Poor adherence with long-term therapies such as lipid lowering therapies is well known and while there is evidence it varies among ethnicities there is no clear evidence as to ethnicity being the sole determinant.[63]

Effect of funding and co-payment on disparities in medicine access and optimal use

It is unclear whether universal coverage, a recent increase in prescription charge (or co-payment), and increases in pharmaceutical funding over the years have reduced disparities in access and optimal medicine use between ethnic groups. Complete data are not readily available to answer these questions.

Using 2005/06 community pharmacy dispensing data, Norris et al did not find significant differences in patterns of dispensing of statins by socioeconomic positions of medicine users.[41] The authors also documented increased use of statins among high-risk groups as a result of stable funding and increased availability of statins. Additionally, the study has shown higher rates of statins use among Māori compared with non-Māori. However, differences in age structure and disease burden between the two ethnic groups were not considered as a bias. As has been discussed above, Māori have higher rates of cardiovascular disorders compared with other groups, and the difference could be attributed to a higher need for statins amongst Māori. Availability of medicines alone does not guarantee access; prescription co-payment also plays a significant role. The findings from an international survey of adults with chronic illness in eight countries showed that 18% of respondents from NZ either did not fill or skipped doses of their prescribed medicines because of prescription costs.[42]

The New Zealand Health Surveys in both 2006/7 and 2012/13 reported significant disparities in the relative risk of having an unfilled prescription due to cost. Māori were 2.3 and 2.8 times more likely have an uncollected prescription due to cost in the respective time periods. This disparity, adjusted for socioeconomic status, age and gender, persists in the face of decreasing rates of uncollected prescriptions for the population as a whole and warrants further investigation.

It has also been noted that a recent increase in prescription co-payment (increased from NZ $3 to NZ $5 since January 2013) could be a barrier for people living in poverty and experiencing significant morbidity to access their regular medicines.[43,44] Findings from 2014/15 NZ annual health survey indicated that Māori adults and Māori children are more than twice as likely as non-Māori adults and non-Māori children, to have an unfilled prescription due to cost, after adjusting for age and sex differences.[44] Additionally, 15% of Māori adults and 9% of Māori children failed to fill prescriptions due to cost. This is concerning; it could further fuel ethnic disparities. Apart from in the context of access, data on the impact of funding/co-payments on the optimal use of medicines are rarely available. Metcalfe's study has shown that for a range of subsidised medicines persistence with prescribed medicines is considerably lower in Māori and Pacific Peoples,[33] but the underlying reasons for these inequities were beyond the scope of their study.

International evidence on the impact of co-payment and financial burdens on medication adherence and persistence is consistent with the above finding. For example, a secondary analysis of data from a prospective randomised control trial in the US, have shown a reduction in disparities in medication adherence rates and clinical outcomes between White and non-White patients for preventive medicines following myocardial infarctions after eliminating any form of co-payments.[45] In a Canadian study, an increase in prescription cost-sharing was also associated with decreased access to essential medicines among older people and adult welfare medication recipients of all ethnic groups, and decrease in essential medicines access in turn associated with increased emergency department visit rates and increased serious adverse events.[46] Generally, as has been discussed above, health disparities between ethnic groups are complex and increasing funding and lowering co-payment can only address some of the underlying causes. A holistic approach that may improve quality of health care and medicine access at all levels for all patients is needed, for example, providing culturally sensitive health care.

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PHARMAC
TE PĀTAKA WHAIORANGA

MEMORANDUM

To SLT

From Therapeutic Group Manager
Chief Advisor, Māori
Manager, Access Equity

Date 23 November 2020

Proposed way forward on proposal to fund two new type 2 diabetes medicines

Recommendations

It is recommended that you:

note that the practical and strategic implications of our approach to this specific transaction are broad and cross functional, requiring significant internal resource

note the options for taking this transaction forward

agree that the next phase of this transaction be managed as a project; and

agree the governance structure for the project; and

note that we will likely require further decisions from the SLT as we progress.

Purpose of Paper

This paper seeks agreement from SLT on the path forward for the type 2 diabetes medicines transaction. This paper provides a summary of options considered and progress made to date following the feedback PHARMAC has received during consultation on the proposal, as well as the key risks and benefits that have been identified.

This paper is not intended to be a comprehensive assessment of the options Instead this is intended to represent a preliminary assessment which can inform the direction we as an organisation should take, balancing the need for expediency with the need to carefully consider the implications at a strategic level of whatever path we choose

Whakatauāki

Ki te kahore he whakakitenga ka ngaro te iwi Without foresight or vision the people will be lost.

As stated in our 2020/21 2023/24 Statement of Intent, this whakatauākī by Kingi Tawhiao Potatau te Wherowhero shows the urgency of unification and strong leadership.

Strategic Direction

The options considered in this paper are intrinsically linked to, and provide us with a unique opportunity to deliver on, our organisational purpose and our 2020 2024 strategic priorities.

Te Tiriti o Waitangi

PHARMAC's commitment, work plan and measures for Te Tiriti o Waitangi are expressed in Te Whaioranga, with accountability measures included in the SOI and SPE

Te Whaioranga expresses PHARMAC's goal as being to honour and actively uphold Te Tiriti across all our work to achieve best health outcomes for Māori within our available resources. Te Whaioranga also expresses our outcomes as:

- Te Tiriti is embedded and is fundamental to PHARMAC's objectives and working culture and sits alongside PHARMAC's purpose;
- Te Tiriti is reflected in the way we plan for, resource, organise and deliver our work as an organisation and we measure and monitor organisational Tiriti compliance;
- All our work delivers for Māori, with Māori, by Māori. This is planned for and appropriately resourced across all directorates.

Strategic priorities

PHARMAC states that we play a key role in an effective and equitable health system We enable equitable access and use of medicines and related products through influencing availability, affordability, accessibility, acceptability, and appropriateness. This paper is of particular relevant to medicines availability in this context Furthermore, we create strong and enduring partnerships across the health system and beyond. The options considered in this paper have important implications for medicine availability and partnerships across the health system

Executive Summary

- We have received strong and valuable feedback through our consultation on a proposal to fund new medicines for type 2 diabetes to the effect that we may not have appropriately considered health inequities and Te Tiriti. As a result of the consultation feedback, we determined, and have communicated, that we could not take the proposal to the Board in October 2020 for a decision on the transaction as planned, since we needed to fully consider the feedback and determine next steps for the proposal. A summary of consultation feedback and the feedback itself can be accessed in Objective (fA268137)
- Reflecting on the process PHARMAC has gone through so far, we consider that the development of the proposal considered health inequities based on the information and expert advice available at the time, but did not give explicit consideration to an ethnicity criterion for this proposal, and we did not meaningfully engage with Māori as a Tiriti partner. PHARMAC does not currently have a clear agreed framework or processes in place to support this consideration or engagement, and the feedback shines a light on this opportunity to improve our capabilities and better engage with Māori in the spirit of partnership.
- Withheld under section 9(2)(h)
  Withheld under section 9(2)(h)
- While we have received consultation feedback in relation to the diabetes transaction, the feedback and our response to it likely has significant implications for PHARMAC's work now and into the future, far beyond the scope of this transaction. Therefore we consider our response to require careful thought and cross organisation involvement

- We consider there to be several options available to PHARMAC Each carry risks and benefits, and therefore trade-offs will be required. We consider that, at a broad level, there are two directions we could take Both would require substantial stakeholder engagement that cannot be managed by one individual member of staff and would require substantial cross organisational support and collaboration. Both would likely require a project management approach

    1. **Proceed** with the transaction broadly as proposed, with amended SA criteria and acknowledgement of the feedback received and a clear organisational commitment to continue our work on medicines access equity, with timeline and reporting commitments included;

       Or

    2 **Delay** this transaction in order to create space to consider more fully the options available to address the equity concerns raised (noting that some work has commenced already, this work may not result in us including an ethnicity criterion, and depending on the specific approach taken this will likely delay the transaction further).

- We consider that PHARMAC should act on the valuable consultation feedback that has been provided and ensure our work on this proposal delivers on our strategic objectives of enabling equitable access and our commitment to Te Tiriti, while minimising any delays to the extent possible. We seek therefore SLT's views on the options. We also anticipate that there will be additional stage-gates in this project where governance decisions will be needed, and some of these may need to be made by the whole of SLT.

Background

Medicine assessment, prioritisation and RFP

We have received clinical advice that Māori, Pacific and South Asian populations are particularly impacted by type 2 diabetes – not only are these population groups more likely to have type 2 diabetes compared with Pākeha, but they are more likely to develop complications from their diabetes, and at an earlier age. We also know through our work in medicines access equity that Māori face systemic barriers that mean they are not able to benefit from medicines in the same way as non-Māori. Although not so extensively studied, Pacific peoples and other groups are likely to face similar barriers.

Over the past few years, we have received and assessed multiple funding applications for medicines in two currently unfunded classes of diabetes treatments, the SGLT-2 inhibitors and the GLP-1 agonists. Our clinical advice indicates that enabling access to a SGLT 2 inhibitor or a GLP-1 agonist for high risk individuals would help to address the unmet need for treatments that address macrovascular complications of type 2 diabetes.

These treatments have been assessed through our health economics team and following prioritisation rank relatively highly on the PHARMAC Options for Investment priority list The rank of the medicines was significantly impacted by the health need of Maori and Pacific peoples, this Factor for Consideration effectively bumping the proposal for targeted funding of the treatments higher up the list.

On 1 January 2020 we released an RFP seeking proposals for sole supply of medicines for type 2 diabetes from the SGLT 2 inhibitor, GLP 1 agonist and/or DPP 4 inhibitor classes We already fund a DPP 4, but not an SGLT 2 inhibitor or GLP 1 agonist

We engaged with a number of key stakeholders prior to the release of the RFP In response to feedback from the sector regarding how the SA criteria could be further improved to enhance equity in access to these medicines, and based on further analysis of local demographic, cardiovascular risk category and HbA1c data, we amended the criteria that had been previously proposed by our clinical advisors and sought additional advice from the Diabetes, Nephrology and Cardiovascular Subcommittees on the updated wording. The wording was further refined on the basis of Subcommittee feedback and then included as proposed SA criteria in the RFP.

Consultation

Following standard PHARMAC processes, we evaluated the RFP bids, negotiated provisional contracts with the preferred suppliers, and on 9 September 2020 released a consultation on a proposal to fund two new medicines.

The proposed Special Authority criteria consulted on were as follows:

> 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 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; 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:
> 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 (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.

Discussion

Consultation feedback

Consultation closed on 8 October 2020 and we received responses from around 60 different individuals, clinician and patient organisations. The feedback received was rich and varied and, while generally very supportive of the funding of the two new medicines, raised some important considerations for PHARMAC relating to our processes for meaningfully considering health and medicines access equity in our funding decisions. A summary of the feedback received is included in Appendix One

Some of the concerns raised in feedback received can be easily addressed by amendments to the proposed special authority criteria, but not all We have already consulted with the Diabetes Subcommittee on some potential amendments to the proposed criteria

Subsequent to the close of the consultation, we met with a number of groups who had raised significant questions, including Te Rōpū Whakakaupapa Urutā (Urutā), Diabetes Foundation Aotearoa and the Pan Pacific Nurses Association. We also offered to meet with the RACP and Te Ohu Rata o Aotearoa (Te ORA) These two groups indicated that our engagement with Urutā would likely represent their views as well.

Equity concerns

The most significant concerns raised by respondents, that are less simple to resolve, relate to access equity matters Urutā's feedback is probably the most comprehensive and reflects sentiments expressed by other submitters. In summary, Urutā submits:

The proposal fails to acknowledge persisting inequities in healthcare access, delivery and outcomes	Urutā discusses the evidence that Māori have reduced access to appropriate preventative healthcare, reduced diagnosis and screening for diabetes, are less likely to be prescribed oral hypoglycaemic therapy or be initiated on insulin, are likely to have higher HbA1c measurements when they are monitored yet get less frequent monitoring and cardiovascular risks assessments all of which are criteria in the proposed special authority. Urutā considers this causes an additional barrier to accessing treatment for Māori
The proposals does not recognise the increased risk of secondary complications in Māori living with type two diabetes	Urutā discusses the evidence that Māori and Pacific peoples are at higher risk of heart and kidney complications due to both the prevalence of type 2 diabetes in Māori and Pacific peoples and that they occur at a younger age. Urutā considers both new drugs should be able to be used concurrently for these reasons
The proposal will increase ethnic inequity in access to medicines	Urutā discusses the proposed listing of 2 new medicines under SA criteria (with an estimated 30% of people eligible), while the current vildagliptin listing is open access as being inequitable as vildagliptin does not have proven cardiovascular outcome benefits Urutā discusses implementation support activities PHARMAC should undertake to promote, educate and actively support primary care to prescribe these medicines as well as monitoring and reporting programme focused on equity Urutā also criticises the make-up of PHARMAC expert advisory committees and challenges PHARMAC to ensure pro equity

	and Hauora Māori capability on its committees.

Urutā recommends open listing of the two new medicines; however, if PHARMAC persists with a SA, it recommends:

- The addition of an equity criteria they suggest "*patient is of Māori or Pacific ethnicity and has an HbA1c above 53mmol/mol*"; and
- Clear messaging about the fact that all practitioners in primary care for apply for the SA
- An active plan to ensure equitable prescribing following the listing

Regardless of the decision, Urutā recommend PHARMAC reviews its processes for equity in funding decisions including seeking an opinion from equity partners earlier in the process

Health equity, Māori health equity and Māori health advancement

It is important to present this paper in the context of the relationship between health equity, Māori health advancement and Māori health inequities. The graphic below is from the Health Quality & Safety Commission and has been adopted by the Ministry of Health it views health equity and Māori health advancement as separate, but interlinked priorities, with Māori health equity an area of commonality and overlap across the two areas.

If we consider and acknowledge the above relationships, some of the consultation feedback we received on the diabetes proposal considers that our current proposal would not promote health equity (for Māori and Pacific), would fall short of delivering on advancing Maori health, and would not address Māori health inequity.

We are being asked by some of our Māori and Pacific stakeholders to use the SA mechanism to:

1. promote **health equity** by actively removing any systemic barriers to equitable health outcomes; and
2. address **Māori health inequities** by actively targeting access to Māori; and
3. advance **Māori health** recognising that Māori have their own health aspirations, priorities, goals and ways of working, and we should aim to partner with and work alongside Māori, offering tools, resources and support to advance Māori health, so all Māori can live long, healthy lives

Stakeholders have indicated to us that they consider the only way to meaningfully achieve these objectives via the SA mechanism is to specifically and actively use ethnicity as a criterion for access.

The challenge we have before us is that the SA mechanism is set up as a fiscal management tool, designed to target investment to those with the greatest potential for health outcomes in accordance with our statutory objective

While initial policy work has been commenced to explore the option of using an ethnicity criterion in SAs to support equity, this has not been completed

In the development of this proposal we set out to passively (rather than actively), address the above three aspects through our SA mechanism. The consultation feedback received to date suggests that a passive approach will not support our strategic priorities of achieving and supporting medicines access equity, but also indicates that we could have a powerful lever to positively influence medicines access equity through our SA mechanism.

Activities over the past couple of weeks

After considering the consultation feedback, and subsequent conversations with these groups, including feedback from Urutā on some proposed changes to the SA criteria, we determined that we would not be able to bring a decision to the PHARMAC Board on 30 October 2020 as originally planned Instead we provided an update to the Board as part of the Pharmaceutical Transactions Report.

Since this time a number of workstreams have been set in motion to identify options for the way forward, confirm legal advice, develop our policy positions on equity considerations, assess budget and cost utility implications of an ethnicity criterion, engagement with CAC, plan stakeholder engagements and scope the project

The communication of the delay to the transaction has been completed, including a notification letter, direct conversations with a number of key stakeholders and consultation respondents and a media release. We have also reached the point where we consider it necessary to decide on a course of action to ensure our work is focussed to achieving the best possible outcome in a timely manner.

The way forward for this transaction

PHARMAC staff have given thought to the various options that could be considered for this transaction Table One below provides an outline of the options PHARMAC staff have considered and some comments on them. We note that amendments to the SA criteria have already been circulated to the Diabetes subcommittee and feedback received to address many of the matters raised in consultation feedback (additions shown in bold, deletions in strikethrough).

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. Patient has not achieved target HbA1c (of less than or equal to 53 mmol/mol) despite maximum tolerated dose of ~~oral diabetic agents and/or insulin~~ **at least one blood glucose lowering agent (eg metformin hydrochloride)** 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
6. **Any of the following:**
   - 6.1. Patient has pre-existing cardiovascular disease or risk equivalent*; or
   - 6.2. Patient has an absolute 5-year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator**; or
   - 6.3. Patient has diabetic kidney disease***; and

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.

	Option	**PHARMAC staff comment**
1	Proceed with the listing as proposed	Withheld under section 9(2)(g)(i) Withheld under section 9(2)(g)(i)
2	Proceed with the listing with above SA criteria amendments to address some matters raised in consultation (but without reference to ethnicity)	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) Withheld under section 9(2)(g)(i) Withheld 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)
3	Proceed with exploring the option of listing with some SA criteria amendments to address some matters raised in consultation (with reference to ethnicity in the context of cardiovascular and renal risk) i.e. instead of the proposed new note above, we add a criterion as follows: Patient is at a high lifetime risk of cardiovascular or renal complications due to their Māori or Pacific ethnicity or their diagnosis with type 2 diabetes at a young age; or	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) Withheld under 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) Withheld under section 9(2)(g)(i) Withheld under section 9(2)(g)(i) Withheld under section 9(2)(g)(i)
4	Proceed with exploring the option of a broad ethnicity criterion as follows: Patient is of Māori or Pacific ethnicity	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) 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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An extensive delay to the funding of these medicines is likely to be perceived negatively by our external stakeholders, and an unnecessary delay to funding would represent health benefits foregone.

Project approach

We anticipate that the next stages of this work would be managed as a project, as there are a number of milestones, and multiple streams of work We would anticipate a project team being formed, with governance from members of the SLT. The exception to this would be if we proceed with the transaction as currently proposed, in which case the transaction would be managed according to usual process, with a parallel communication plan

Given the potential implications of the transaction and parallel workstreams to the organisation, we propose that the governance team would be:

- Director of Operations
- Director of Engagement and Implementation
- Chief Advisor Māori
- Chief Executive

There may also be stage gates which require decision from the whole of SLT. We propose that the project team (or sub teams) would include representation from the following PHARMAC teams:

- Pharmaceutical Funding
- Access Equity & Te Whaioranga Programme Lead

- Deputy Medical Directors
- Health Economics & Analysis
- Schedule Strategy and Development
- Communications & Implementation Programmes
- Policy
- Legal

Legal Advice ***Confidential and Legally Privileged Legal Advice from PHARMAC's legal advisors***

Consultation

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Consultation and engagement

The development of this paper has been in collaboration with members of PHARMAC staff from across the organisation including Operations, Medical, Engagement and Implementation, Analysis and Legal Services. We have taken into account the consultation feedback we received on the original proposal and the additional views shared with us by the respondents we engaged with after consultation closed

The Policy Leadership Team (PLT) has previously been consulted on the use of ethnicity criterion in special authorities, and the Policy team are working on a framework proposal that it plans to bring to SLT.

At its meeting on 6 November 2020, the Consumer Advisory Committee (CAC) considered a paper on the diabetes medicines transaction and some of the considerations we now face.

Pharmacology and Therapeutics Advisory Committee (PTAC) and relevant Subcommittees (diabetes, cardiovascular and nephrology) will be engaged as part of the further work on the chosen option

Our kaumatua has been involved in some of the recent stakeholder engagement, and it is anticipated that Te Rōpū Awhina Māori (TRAM) could also be engaged as part of the further work on the chosen option.

The consultation on the original proposal enabled us to identify Te Rōpū Whakakaupapa Urutā (Urutā) as an important stakeholder group for PHARMAC. While in name this group is the National Māori Pandemic Group and formed in response to the COVID 19 pandemic, this group is now focussing its work on health inequities more broadly Urutā is made up of some of the nation's leading Māori medical and health experts including Primary Care Specialists, Public Health experts, Public Health Physicians, Nurses, and iwi leaders. The Māori Medical Practitioners Association (Te ORA), and the RACP have indicated to us that Urutā are in a position to also represent their views on the diabetes proposal. We have had two meetings with Urutā subsequent to consultation, and this group will be critical in our ongoing work on this transaction and our equity work as we look to improve our capability to uphold the articles of Te Tiriti o Waitangi. We have also held meetings with a number of other stakeholders subsequent to consultation, including the Pan Pacific Nurses Association We consider these groups likely to be strongly supportive of option one proposed above and would engage directly on the topic based on the approach agreed by the SLT.

Te Tiriti implications

Feedback from Māori is overall supportive of funding these medicines However, there is concern from Māori, raised during consultation on this proposal, that the SA criteria may further disadvantage Māori for a variety of reasons and that we should have sought stronger Māori input into the design, development and decision of the proposal Whichever our path forward, we will need to more actively partner with Māori.

Communications plan – Diabetes medicines notification

Date updated:	15 December 2020
Communications lead:	Jane Wright
Subject matter expert:	Elena Saunders
Media spokesperson:	Sarah Fitt

Background

PHARMAC is making a decision on funding empagliflozin (Jardiance) and empagliflozin with metformin (Jardiamet), supplied by Boehringer Ingelheim and dulaglutide (Trulicity), supplied by Eli Lilly.

In September 2020 we sought feedback on a proposal to fund these treatments from 1 December 2020 The consultation closed on 2 October and we received rich and varied feedback from around 60 different individuals, professional societies and advocacy groups. While the consultation feedback was, in general, strongly supportive of funding the two medicines, there were a number of questions raised, including questions around medicines access equity, especially for Māori and Pacific people

As a result, we were not able to take the decision to the Board to enable a 1 December listing We communicated about that on 5 November with a notification to our stakeholders and a media release. We followed up with an update on 7 December indicating the PHARMAC Board would be making a decision in January 2021.

We have received requests for copies of the submissions provided in response to our consultation, but these were declined on the grounds that, as a decision has not yet been made for the proposal, the withholding of the information is necessary to carry on negotiations without prejudice or disadvantage. Since consultation closed, we have been carefully considering the feedback received, including the most complicated theme, which was equitable access to the medicines. We have met with equity partners and key stakeholders and determined that the inclusion of an ethnicity criterion in the Special Authority will support achieving equitable access to these medicines. While we can't guarantee the numbers, we estimate that this will mean that an additional 5,000 people will be able to access these medicines because of this inclusion. We estimate up to 53,000 people overall will access these treatments.

We planned to go to the PHARMAC Board for a decision at their next physical meeting in January 2021. However, they have offered agreed to consider the funding proposal outside their normally scheduled meetings, to ensure that a decision could be made as quickly as possible.

On Friday 18 December the PHARMAC board will make a decision on funding the two medicines. If approved, people with type 2 diabetes who meet the Special Authority criteria will be able to access empagliflozin (Jardiance) and empagliflozin with metformin (Jardiamet) from 1 February 2021 and dulaglutide (Trulicity) once it has Medsafe approval.

Communications objectives

The purpose of this communications plan is to:

- communicate the decision, with a key focus on channels that reach Māori and Pacific people who may benefit from treatment,
- reassure key Māori stakeholders that this decision is focused on achieving equitable access to these medicines for Māori and that this is a key focus for PHARMAC, and
- respond to questions in relation to this decision (note: PHARMAC staff are currently pulling together Q&A documentation to support any notification).

Recommended communications approach and timings

We intend to proactively promote this funding decision and the rationale for the changes to the Special Authority criteria Our media release will be in both English and Te Reo Māori. We will have two internal media spokespeople Sarah Fitt for mainstream and Pacific media and Trevor Simpson for Māori media We will also offer up an opportunity to talk with Diabetes Subcommittee Chair Dr Sean Hanna (fluent in Te Reo), who can explain what this will mean for people with diabetes and their health care professionals. He will be speaking as a healthcare professional AND an advisor to PHARMAC, not as a PHARMAC representative. We will release all the consultation feedback, under OIA, and point anyone interested in reading the feedback to our website.

Friday 18 December

We anticipate the board will have made a decision on funding the two medicines by 1000 on funding the two medicines.

Assuming Board approval, from 1030 we will communicate the decision directly with those in the following cascade chart, in the order they are listed They will be advised that the information is embargoed until Monday 21 December at 0900 Media sent the embargoed information will be offered interview opportunities on Monday.

Communication cascade		
Stakeholder/Audience	**What are they getting**	**Person who sends/does**
Suppliers Boehringer Ingelheim and Eli Lilly	Phone call, followed by the embargoed media release (in both English and Te Reo) and notification	Elena Saunders
Ministry of Health, including Medsafe		Alison Hill
Minister and Associate Minister Henare's offices Press Secs		Jane Wright
Diabetes Subcommittee Chair, Dr Sean Hanna		Elena Saunders
Te Karere Withheld under section 9(2)(a)		Jane Wright

Maori TV Withheld under section 9(2)(a) Withheld under section 9(2)(a)		
Radio Waatea Withheld under section 9(2)(a)		
Radio NZ Pacific Withheld under section 9(2)(a)		
Radio 531PI breakfast Withheld under section 9(2)(a) (confirm personal contact before sending embargoed info)		

Monday 21 December

At 0900 we will communicate the embargoed decision with those in the following cascade chart, in no particular order:

Communication cascade		
Stakeholder/Audience	**What are they getting**	**Person who sends/does**
PTAC and Diabetes, Cardiovascular and Nephrology Subcommittees	Embargoed media release (in both English and Te Reo) and notification	Elena Saunders
Heather Verry, Chief Executive - Diabetes NZ		
CAC		Janet Mackay
Dr Helen Snell, chair of NZSSD		Elena Saunders
Withheld under section 9(2)(g)(i) Withheld under section 9(2)(g)(i) Withheld under section 9(2)(g)(i) of Te Rōpū Whakakaupapa Urūtā		Elena Saunders
Dr Bryan Betty, MD of RNZCGP		
Dr Jeremy Krebs		
Dr John Baker, Diabetes Foundation Aotearoa	Phone call	Elena Saunders (with Sarah Fitt if available)

The notification and media releases (English and Te Reo versions) will go up on our website at 1200 Media will be offered interviews Monday afternoon and Tuesday morning A link to the notification will then be sent to our identified stakeholders including all individuals or groups that responded to the consultation, healthcare professionals, consumer groups and media see cascade list below

Communication cascade		
Stakeholder/Audience	**Distribution channel** (all cover messages link to the web content)	**Person who sends/does**
Base content for all	https://pharmac.govt.nz/news and resources/news/?type=10&page=1	Liz
Everyone who has subscribed to receive "consultation", which includes advocacy groups	Via MailChimp	Lisa Martin
Everyone who responded to the consultation	Via email	
Hospital Pharmacists DHB GMs P&F, COOs & Pharmacy Portfolio Managers	Include message in weekly Thursday email to Chief Hospital pharmacists Ask TAS to circulate	Lisa Crawford on behalf of Lisa
CMOs	Via email	Trish
Community Pharmacists	Mailchimp community pharmacy audience list (740) Mostly pharmacy owners.	Lisa Martin
	The Pharmaceutical Society + the Guild	Sarah K
Māori healthcare sector	NZNO, Māori Nurses Māori Pharmacists Māori Doctors Te ORA Māori Allied Health Workers	Lisa Crawford, to send on behalf of Shirley
GP and other prescribers	We do not have direct channels to GPs. We need to ask the following to cascade our message to their members: Jane to give Rongo and Trish cover messages Royal NZ College of General Practitioners (CEO Lynne Hayman and Cc: Bryan Betty) Royal; Australasian College of Physicians, NZ (Dr George Laking, Aotearoa New Zealand President Withheld under section 9(2)(a) Withheld under section 9(2)(a)	

	NZMA (CEO Lesley Clarke) Primary Health Alliance (CEO Sharron Harris) RGPN Nurse practitioners via generic admin emails NZNO Health Pathways Justine Lancaster Withheld under section 9(2)(a)	
Media	Via media release	Jane (email) and Liz Barlow (website)
Social media	Facebook and Twitter	Sarah K

Key messages

Umbrella statement

PHARMAC has approved funding for two new medicines with substantial health benefits for around 53,000 New Zealanders with type 2 diabetes.

Core messages

- We are aware of the keen interest of many people with type 2 diabetes, and those who provide them with clinical care, in having new treatments funded as soon as possible
- Evidence suggests these medicines do more than just reduce sugar levels in people with high-risk type 2 diabetes. They can also help manage address type 2 diabetes-related complications like kidney and heart disease in people who are at high risk of these complications
- PHARMAC's Board has made a decision that means people with high-risk type 2 diabetes, who meet funding criteria, will be able to access funded empagliflozin (with or without metformin) from 1 February 2021. They will also be able to get funded Dulaglutide once it has Medsafe approval
- People with diabetes, their whānau and health professionals told us that there is a need for these effective medicines to be funded to help manage the growing health problem of type 2 diabetes in Aotearoa New Zealand.
- The gross cost to the combined pharmaceutical budget for these two medicines is estimated to be roughly $125 million over 5 years.
- We had originally proposed to fund empagliflozin (with and without metformin) from 1 December 2020, however we received a substantial amount of consultation feedback that took us some time to work through. After carefully considering the consultation feedback we made some changes to the Special Authority criteria we originally proposed These changes to the criteria aim to make sure that people with type 2 diabetes who are at high risk of heart and kidney complications can access these treatments
- We have also made the decision to specifically name Māori and Pacific ethnicities within the funding criteria. This is the first time we have included this wording in Special Authority criteria. This is an intentional move to proactively promote equity of access to these treatments for population groups who are at high risk of complications of type 2 diabetes and

for whom there is direct evidence of inequities in access to medicines We would like to thank the people and organisations who contributed important feedback that supported this decision

- We know that funding medicines does not in itself address many of the barriers to access that people face. There are lots of structural issues in the health system that PHARMAC cannot address by itself with this funding decision. We acknowledge that health inequities are unable to be addressed by medicines alone, and that these medicines are focussed on treatment, rather than prevention but we also know that PHARMAC does have a role to play
- You can read more about our medicines access equity work here.
- This is the first time we have included ethnicity in Special Authority criteria. We intend to explore and engage with the sector on a policy approach for considering including ethnicity in Special Authority criteria for a wider range of medicines, early in 2021.
- PHARMAC is committed to continuing our work to fund more medicines for more people, delivering the best possible health outcomes for New Zealanders from within our fixed budget.

Excerpt from PHARMAC weekly key messages

Updated Thursday 17 December 2020

New diabetes treatments notification

Background

The PHARMAC Board have approved funding for empagliflozin (Jardiance) and empagliflozin with metformin (Jardiamet), supplied by Boehringer Ingelheim and dulaglutide (Trulicity), supplied by Eli Lilly. We are intending to share their decision publicly on Monday 21 December

Communications approach

We intend to proactively promote this funding decision and the rationale for the changes to the Special Authority criteria. We will have two internal media spokespeople Sarah Fitt for mainstream and Pacific media and Trevor Simpson for Māori media We will also offer up an opportunity to talk with Diabetes Subcommittee Chair Dr Sean Hanna (fluent in Te Reo), who can explain what this will mean for people with diabetes and their healthcare professionals He will be speaking as a healthcare professional AND an advisor to PHARMAC, not as a PHARMAC representative. We are also seeking a person with diabetes to share what this will mean for them. We will release all the consultation feedback, under OIA, and point anyone interested in reading the feedback to our website.

Umbrella statement

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Core messages

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- Evidence suggests these medicines do more than just reduce sugar levels in people with high risk type 2 diabetes. They can also help manage address type 2 diabetes related complications like kidney and heart disease in people who are at high risk of these complications.
- PHARMAC's Board has made a decision that means people with high risk type 2 diabetes, who meet funding criteria, will be able to access funded empagliflozin (with or without metformin) from 1 February 2021 They will also be able to get funded Dulaglutide once it has Medsafe approval.
- People with diabetes, their whānau and health professionals told us that there is a need for these effective medicines to be funded to help manage the growing health problem of type 2 diabetes in Aotearoa New Zealand.
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proposed. These changes to the criteria aim to make sure that people with type 2 diabetes who are at high risk of heart and kidney complications can access these treatments

- We have also made the decision to specifically name Māori and Pacific ethnicities within the funding criteria This is the first time we have included this wording in Special Authority criteria. This is an intentional move to proactively promote equity of access to these treatments for population groups who are at high risk of complications of type 2 diabetes and for whom there is direct evidence of inequities in access to medicines We would like to thank the people and organisations who contributed important feedback that supported this decision.
- We know that funding medicines does not in itself address many of the barriers to access that people face. There are lots of structural issues in the health system that PHARMAC cannot address by itself with this funding decision. We acknowledge that health inequities are unable to be addressed by medicines alone, and that these medicines are focussed on treatment rather than prevention, but we also know that PHARMAC does have a role to play
- You can read more about our medicines access equity work here.
- This is the first time we have included ethnicity in Special Authority criteria. We intend to explore and engage with the sector on a policy approach for considering including ethnicity in Special Authority criteria for a wider range of medicines, early in 2021
- PHARMAC is committed to continuing our work to fund more medicines for more people, delivering the best possible health outcomes for New Zealanders from within our fixed budget.

PHARMAC
TE PĀTAKA WHAIORANGA

MEMORANDUM FOR OUT OF CYCLE BOARD MEETING DECEMBER 2020

To: PHARMAC Directors

From: Chief Executive

Date: December 2020

Proposal to fund two new medicines for type 2 diabetes

Recommendations

It is recommended that, having regard to the decision-making framework set out in PHARMAC's Operating Policies and Procedures, you:

resolve to approve the amendments to the Pharmaceutical Schedule relating to empagliflozin (with and without metformin) and dulaglutide as set out in Appendix One of this Board Paper;

note that this proposal is for a 1 February 2021 list date for empagliflozin (with and without metformin), and for a list date for dulaglutide as soon as practical after Medsafe approval;

resolve to approve the 10 December 2020 agreement with Boehringer Ingelheim NZ Limited;

resolve to approve the 27 August 2020 agreement with Eli Lilly and Company (NZ) Limited;

resolve that the consultation on this proposal (including further engagement with submitters) was appropriate, and no further consultation is required;

note that, as a result of feedback received in the consultation process for this proposal, PHARMAC staff are undertaking policy work to consider how special authority funding criteria could be used as a lever to support the elimination of health inequities, including a specific ethnicity criteria for Māori and Pacific people;

note that this proposal involves reference to specific ethnicities (Māori and Pacific people) within the Special Authority and that this would be the first time this has been used by PHARMAC as part of funding criteria;

note that the additional steps PHARMAC staff took to more fully engage with Māori stakeholders, following the close of the consultation period, reflects our commitment to honour and uphold Te Tiriti o Waitangi together with equity and partnership as an overall goal; and

note the engagement and implementation activities completed to date to support the funding of these medicines, and the further activities planned, including monitoring and evaluation of access to these medicines.

SUMMARY OF OVERALL PROPOSAL				
Market data	**Year ending**	**30 Jun 2021**	**30 Jun 2022**	**30 Jun 2023**
	Total number of patients	18,114	45,729	52,800
	Number Māori or Pacific people	9,235	23,314	26,918
Community Pharmaceutical Expenditure	Subsidy (gross)	Withheld	Withheld	Withheld
	Net cost of community pharmaceuticals	Withheld	Withheld	Withheld
	Net present value	Withheld		
Hospital Pharmaceutical Expenditure	Expenditure (gross)	Withheld	Withheld	Withheld
	Net cost to DHBs	Withheld	Withheld	Withheld
	Net present value	Withheld		
TOTAL - Combined Pharmaceutical Budget (CPB)	Net cost to CPB	Withheld	Withheld	Withheld
	Net present value	Withheld		
Other DHB costs	Net distribution costs	$270,000	$1,170,000	$1,620,000
	Other DHB costs/(savings)	($1,250,000)	($7,160,000)	($8,110,000)
Total	Total cost to DHBs	Withheld	Withheld	Withheld
	Net present value cost to DHBs	Withheld		

Notes:

1 Number of patients affected = number of patients accessing one of the new treatments in each financial year
2 Subsidy (gross) = forecast of spending at the proposed subsidies
3. Net cost to Schedule = forecast of change in total spending on pharmaceuticals listed on the Schedule compared with status quo
4. Other DHB costs = forecast change in health sector costs based on costs of managing diabetes complications
5 All costs are expressed ex manufacturer, excluding GST
6. NPV is calculated over 5 years using an annual discount rate of 8%
7. Calculations in A1451104

SUMMARY OF PHARMACEUTICAL: EMPAGLIFLOZIN +/- METFORMIN			
Brand name	Jardiance Jardiamet	**Chemical name**	Empagliflozin Empagliflozin with metformin
Therapeutic Group	Diabetes	**Presentation**	Tablet
Supplier	Boehringer Ingelheim	**Pharmaceutical type**	New Chemical Entity
MoH Restriction	Prescription Medicine	**Proposed restriction**	Special Authority

Presentation pack size	**Proposed subsidy**	**Net Price**
Empagliflozin tab 10 mg – 30	$58.56	Withheld
Empagliflozin tab 25 mg – 30	$58.56	Withheld
Empagliflozin tab 5 mg with 500 mg metformin 60	$58 56	Withheld
Empagliflozin tab 5 mg with 1,000 mg metformin – 60	$58.56	Withheld
Empagliflozin tab 12 5 mg with 500 mg metformin 60	$58 56	Withheld
Empagliflozin tab 12 5 mg with 1,000 mg metformin 60	$58 56	Withheld

Market data	**Year ending**	**30 Jun 2021**	**30 Jun 2022**	**30 Jun 2023**
Number of patients		17,616	41,982	47,520
No Māori or Pacific people		8,981	21,403	24,227
Community Pharmaceutical Expenditure	Subsidy (gross)	Withheld	Withheld	Withheld
	Net cost to Schedule	Withheld	Withheld	Withheld
	Net present value	Withheld		
Hospital Pharmaceutical Expenditure	Expenditure (gross)	Withheld	Withheld	Withheld
	Net cost to DHBs	Withheld	Withheld	Withheld
	Net present value	Withheld		
Other DHB costs	Net distribution costs	$220,000	$940,000	$1,290,000
	Net other costs/ (savings)	($1,250,000)	($7,160,000)	($8,100,000)
Total	Total cost to DHBs	Withheld	Withheld	Withheld
	Net present value	Withheld		

Notes:

1 Number of patients = total number of patients accessing empagliflozin or empagliflozin with metformin in each financial year
2. Subsidy (gross) = forecast of spending at the proposed subsidies
3. Net cost to Schedule = forecast of change in total spending on pharmaceuticals listed on the Schedule compared with status quo, including offset of metformin single agent presentation
4 Other DHB costs = forecast change in health sector costs based on costs of managing diabetes complications
5. All costs are expressed ex manufacturer, excluding GST
6. NPV is calculated over 5 years using an annual discount rate of 8%.
7. Calculations in A1451104

SUMMARY OF PHARMACEUTICAL: DULAGLUTIDE			
Brand name	Trulicity	**Chemical name**	Dulaglutide
Therapeutic Group	Diabetes	**Presentation**	Injection
Supplier	Eli Lilly	**Pharmaceutical type**	New Chemical Entity
MoH Restriction	Prescription Medicine	**Proposed restriction**	Special Authority

Presentation pack size	**Proposed subsidy**	**Price**
Dulaglutide inj 1.5 mg per 0.5 ml prefilled pen - 4	$115.23	$115.23

Market data	**Year ending**	**30 Jun 2021**	**30 Jun 2022**	**30 Jun 2023**
Number of patients		498	3,747	5,280
No. Māori or Pacific people		254	1,910	2,692
Community Pharmaceutical Expenditure	Subsidy (gross)	Withheld	Withheld	Withheld
	Net cost to Schedule	Withheld	Withheld	Withheld
	Net present value	Withheld		
Hospital Pharmaceutical Expenditure	Expenditure (gross)	With	Withheld	Withheld
	Net cost to DHBs	With	Withheld	Withheld
	Net present value	Withheld		
Other DHB costs	Net distribution costs	$9,000	$160,000	$290,000
	Net other costs/(savings)	($243)	($4,000)	($6,000)
Total	Total cost to DHBs	Withheld	Withheld	Withheld
	Net present value	Withheld		

Notes:

1. Number of patients = total number of patients accessing dulaglutide in each financial year
2. Subsidy (gross) = forecast of spending at the proposed subsidies
3. Net cost to Schedule = forecast of change in total spending on pharmaceuticals listed on the Schedule compared with status quo, including offset of metformin single agent presentation
4. Other DHB costs = forecast change in health sector costs based on costs of managing diabetes complications
5. All costs are expressed ex manufacturer, excluding GST
6. NPV is calculated over 5 years using an annual discount rate of 8%
7. Calculations in A1451104

Executive Summary

- The proposal is to fund two new treatments for type 2 diabetes through provisional agreements with two suppliers[1], following a request for proposals, as follows:
    - empagliflozin (Jardiance) and empagliflozin with metformin (Jardiamet), oral tablets, supplied by Boehringer Ingelheim, with funding to start from 1 March 2021; and
    - dulaglutide (Trulicity), a self administered injection, supplied by Eli Lilly, with funding to start as soon as practicable following Medsafe approval

- Empagliflozin is a sodium glucose transport protein 2 (SGLT 2) inhibitor, and dulaglutide is a glucagon like peptide 1 receptor (GLP 1) agonist Both these medicines offer benefits for people at high risk of certain complications of type 2 diabetes (including Māori and Pacific people), beyond what can be achieved with currently funded medicines. We anticipate that this would be roughly 53,000 people in Aotearoa New Zealand.

- Special Authority (SA) criteria developed in consultation with stakeholders from across the sector are proposed to be applied to empagliflozin (with and without metformin) and dulaglutide The proposed SA criteria have been amended following careful consideration of consultation feedback, including matters related to medicines access equity. The proposed SA criteria specifically name Māori and Pacific ethnicities which, if approved, would be the first time ethnicity is used by PHARMAC as a criteria for access to funded medicines We consider this to be an intentional action to improve medicines access equity for populations who experience substantial access and outcomes disparity in type 2 diabetes; a pro-equity approach, and a demonstration of PHARMAC's stated commitment to the articles of Te Tiriti o Waitangi. We estimate an additional 4,800 Māori or Pacific people would access these medicines under the criteria we are proposing compared to the version consulted on

- The overall cost-effectiveness of this proposal is estimated to be in the likely range of Withheld (possible range Withheld) QALYs per million dollars, and it would help to meet significant unmet health needs for people with type 2 diabetes who are at high risk of cardiovascular and renal complications.

- This proposal to fund both a SGLT-2 inhibitor (empagliflozin) and a GLP 1 agonist (dulaglutide) using SA criteria is currently ranked at Withheld under on the Options for Investment priority list (as at December 2020). A proposal to fund just a SGLT 2 inhibitor via SA is currently ranked at Withheld on the Options for Investment priority list (as at December 2020) and, if this proposal is approved, would be superseded and so removed from the priority list.
- This proposal involves new investments totalling a total net cost of Withheld under to the Combined Pharmaceutical Budget (CPB) over 5 years, with an overall investment by DHBs of Withheld under once distribution, service delivery costs and offsets of sector savings (including reductions in the costs to DHBs for heart failure hospitalisations and renal replacement), have been factored in (all figures are versus status quo, 5 year NPV, 8% discount rate)

- This proposal, in addition to our current forecasted expenditure, would exceed our available funding for 2021/22 and beyond. We note that this is not uncommon for the out years for large investment proposals, given the nature of our budgeting cycle. We expect to manage this risk through our usual processes, including anticipated budget uplifts and future savings transactions.

[1] Copies of the agreements can be made available to any Board member on request.

Why proposal should not be considered under Delegated Authority

The estimated Financial Impact (NPV) of this proposal is more than $10,000,000 of the Pharmaceutical Budget. The Financial Impact (NPV) is calculated on the basis of the net present value of the proposed subsidy (ex manufacturer exclusive of GST) over five years at a discount rate of 8% to be paid by the funder for the products and the forecast demand, taking into account any effect of the decision on that demand, versus the status quo.

Strategic Direction

The proposal is for the listing of new medicines in the Pharmaceutical Schedule, which aligns with PHARMAC's overall objective to deliver the best health outcomes from Aotearoa New Zealand's investment in medicines and medical devices from within the funding provided.

The proposal takes into consideration the considerable unmet need in Aotearoa New Zealand for diabetes treatments that can reduce the adverse outcomes of type 2 diabetes, including the Hauora Arotahi Māori health areas of focus, with access targeted to those priority populations at highest need and most likely to benefit We consider this proposal to be pro equity, and well aligned with three of our strategic priorities. Diabetes treatments are identified as a particular focus of our medicines access equity strategic priority, which also identifies priority populations that include Māori and Pacific people.

Background

The number of people in Aotearoa New Zealand living with type 2 diabetes is rising. A number of medicines for the management of type 2 diabetes are currently funded via the Pharmaceutical Schedule. Broadly speaking, the medicines currently funded for type 2 diabetes work by improving glycaemic control. Improved glycaemic control can address some, but not all, of the complications of diabetes Glycamic control over time is generally measured by a blood test of glycosylated haemoglobin (HbA1c). The usual target for glycaemic control in people with type 2 diabetes is 53 mmol/mol or less.

We have received feedback from the health sector and from our clinical advisors that there is a compelling need to fund an SGLT-2 inhibitor and a GLP-1 agonist as these medicines can help reduce the risk of cardiovascular and renal complications in people with type 2 diabetes at high risk of these complications, and that appropriate funding of these medicines represents an opportunity to respond to the health inequities that are experienced by Māori and Pacific people with type 2 diabetes.

Over the past few years we have received and assessed multiple funding applications for medicines in the SGLT-2 inhibitor and the GLP-1 agonist classes. Our clinical advice (see below) indicates that enabling access to either a SGLT 2 inhibitor or a GLP 1 agonist for high risk individuals would help to address this unmet need, and these treatments rank relatively highly on the Options for Investment priority list.

In March 2019, the Diabetes Subcommittee recommended that antidiabetic agents be funded for the improvement of cardiovascular outcomes in type 2 diabetes patients with established CVD subject to proposed SA criteria.

Engagement with stakeholders prior to RFP

PHARMAC staff engaged with a number of key stakeholders prior to the January 2020 release of the RFP for these medicines. Examples of key engagement activities were as follows:

- In May 2019, staff met with a combined group of diabetes stakeholders, while attending the New Zealand Society for the Study of Diabetes (NZSSD) annual scientific meeting This meeting included representatives of the patient advocacy group Diabetes New Zealand, as well as paediatric and adult diabetes clinician groups. The proposed SA criteria were presented, and feedback was sought The attendees acknowledged that the criteria were intended to target access to those people with the highest need and discussed the need for a specific renal criterion
- In June 2019, staff met with the New Zealand Cardiac Network. Again, the proposed SA criteria were presented and discussed The attendees considered the proposed cardiovascular risk threshold of 20% to be too high, and considered 15% would be more appropriate. The attendees also felt that the use of SA criteria was appropriate, but that there should be no restriction on prescriber type. The attendees also suggested that engagement across diabetes, cardiovascular and renal clinician groups would be important.
- In August 2019, staff met with the Ministry of Health's National Diabetes Leadership Group2. At this meeting the proposed SA criteria were presented and discussed. The Group considered that it was important to include SA criteria in order to target these medicines to the groups at highest need, particularly in the absence of national treatment guidelines. The Group discussed the challenge of balancing five year and lifetime cardiovascular risk, and the absence of a validated lifetime risk calculator
- In October 2019, staff participated in a multi-stakeholder meeting with representatives from diabetes, cardiology and renal clinician groups This included in-depth discussion of the proposed SA criteria, and how these could be further refined with a view to enhancing medicines access equity. Subsequently, attendees summarised their views of the proposed SA criteria in a letter to PHARMAC, together with endorsement or additional commentary from the represented societies and organisations. This letter is available on request.

In response to the pre RFP feedback from the sector regarding how the SA criteria could be further improved to enhance equity in access to these medicines, and based on further analysis of Aotearoa New Zealand demographic, cardiovascular risk category and HbA1c data, we amended the criteria that had been proposed by the Diabetes Subcommittee and sought additional advice from the Diabetes, Nephrology and Cardiovascular Subcommittees on this updated approach. The approach was further refined on the basis of Subcommittee feedback and updated SA criteria were included in the RFP

Commercial process

Given the level of competition in this market, we determined that a competitive process (a Request for Proposals (RFP)) would be an appropriate approach to securing funding of one or more of these new treatments. However, given the indicative pricing in the funding applications, there were concerns around PHARMAC's ability to afford open listing of these products, so we sought bids for both open and restricted access (via SA criteria).

On 1 January 2020 we released an RFP seeking proposals for sole supply of diabetes medicines from the SGLT 2 inhibitor, GLP 1 agonist and/or DPP 4 inhibitor classes Suppliers were required to submit proposals under various funding scenarios depending on the diabetes medicine class In the case of SGLT 2 inhibitors and GLP-1 agonists, the scope was limited to medicines that had established evidence of cardiovascular benefit.

[2] The NDLG comprises members from across the diabetes sector and includes Māori representation. The Group provides leadership to the sector and advice to the Ministry to support implementation and delivery of the Ministry of Health's Diabetes Plan. The NDLG oversees the strategic direction, supports accountability and is a core advisor on the delivery of the Diabetes Plan. To achieve this purpose the NDLG provides proactive expert advice to the Ministry on the implementation of the Diabetes Plan including; improving equity and reducing ethnic disparities in outcomes, improving the detection of diabetes, slowing the disease's progression, increasing the quality of life for people with diabetes, improving clinical outcomes for people with, or at risk of, diabetes, preventing and/or delaying the onset of diabetes and improving consistency of service provision.

On 3 February 2020, while the RFP was still open, we ran a supplier RFP briefing meeting in Auckland This meeting identified a desirable process improvement that was expected to improve competitiveness and future funding flexibility for PHARMAC On 13 February 2020 we issued an addendum to the RFP that:

- extended the initial sole supply period offered through the process by one year (until 30 June 2024); and
- included an option to extend the sole supply period by mutual consent by two additional 12 month periods

This means the latest end to sole supply through this process would be 30 June 2026.

We received proposals from six different suppliers for the supply of nine different medicines. Following an initial evaluation of the proposals received, additional clinical advice was sought from the Diabetes Subcommittee Following consideration of this advice, two medicines were excluded from further analysis on the basis that they did not have established evidence of cardiovascular benefit and therefore did not meet the scope requirements of the RFP.

An Evaluation Committee comprising PHARMAC staff evaluated each Proposal Set to select its preferred proposal(s) using the evaluation criteria outlined in the RFP. The Evaluation Committee selected a preferred funding scenario and preferred proposals within that Boehringer Ingelheim's proposal for the sole supply of a SGLT-2 inhibitor (empagliflozin with and without metformin) subject to SA criteria, Eli Lilly's proposal for the sole supply of a GLP 1 agonist (dulaglutide) subject to SA criteria, and Novartis' proposal for the sole supply of a DPP-4 inhibitor (vildagliptin with and without metformin) were identified as the preferred combination of proposals. Minutes of the RFP Evaluation Committee meetings are available to Board members on request The preferred proposal for the sole supply of a DPP 4 inhibitor had a limited budgetary impact (savings in the order of $1.5 million 5 year NPV), was not considered contentious and is being progressed as a separate decision under delegated authority

We note, for the sake of completeness, that the timeline for decision making on this RFP has been considerably longer than expected. This has been due to a number of factors including, but not limited to, the complexity of the evaluation, uncertainty around our 2019/20 and 2020/21 budget position, diversion of internal resources due to COVID 19, and additional time required to ensure careful consideration of consultation feedback.

As detailed in the next section, we have made some changes to the proposed SA criteria following consideration of consultation feedback, and the implementation dates would be slightly later (i.e. two months) than originally considered in our evaluation of the RFP proposals We have considered whether, from a procurement perspective, these changes could have any impact on the Evaluation Committee's rationale for selecting the preferred proposals. We consider that the modifications would apply equally to all proposals considered and, therefore, there is no need to revisit the evaluation process All key factors noted by the RFP Evaluation Committee as being pertinent to the selection of proposals remain unchanged. We have therefore not re-evaluated the proposals.

Changes in response to consultation feedback – focusing on equity

We released a consultation on this proposal on 9 September 2020 and received a wide variety of responses Further detail of responses can be found in the Consultation section of this paper, and the compiled responses are provided in Appendix Two.

A number of responses to consultation raised the topic of health equity, particularly for Māori and Pacific people. Some respondents considered that the proposal represented a positive step forward for health equity, whereas others considered that the proposed SA criteria would represent a barrier to achieving health equity in particular for Māori and Pacific people.

In general terms, the latter respondents considered that Māori and/or Pacific people would be less likely to qualify for treatment under the proposed criteria than non-Māori, non-Pacific. This was in contrast to our original analysis, which indicated that Māori and Pacific would represent a higher proportion of eligible patients (i e , roughly 45% of eligible patients) than is represented in the overall population (i.e., roughly 25% of the population of Aotearoa New Zealand). Our analysis was subsequently independently confirmed by work published in October 2020 by Vitz et al in the New Zealand Medical Journal[3], who considered the criteria issued by PHARMAC for consultation feedback in September 2020 to be pro-equity.

However, other feedback has expressed the view that this proposal did not go far enough, as sector barriers to access would remain and PHARMAC staff consider these would be overcome, at least to some small extent, by the inclusion of ethnicity in the SA criteria

Given the nature of the feedback received, we contacted a number of respondents to further understand their concerns, and to ensure that any changes we made to the proposal would carefully and meaningfully address them. PHARMAC staff met, via videoconference, with multiple stakeholder groups, who have clearly articulated a view that systemic inequities in health care access for Māori and Pacific people mean that a more active approach than originally proposed is needed to meaningfully respond to the inequitable outcomes experienced by Māori and Pacific people with type 2 diabetes.

Following careful consideration of that feedback, we have made changes to the original proposed SA criteria to specifically include ethnicity as one aspect of an overall set of clinical criteria (we are not proposing ethnicity as a qualifying criterion in its own right) We sought legal advice on including ethnicity in SA criteria (which is summarised below in the Legal Advice section of this paper). In the absence of a current policy for when to apply SA criteria, we used the legal advice as a framework to support consideration of whether use of an ethnicity criterion is legally, and otherwise, justifiable. We are satisfied that all the requirements outlined in the legal advice have been considered through our work and the consultation process A summary of our considerations is included in Table 1 below

A programme of work to develop PHARMAC policy on this matter has now commenced, which includes consideration of our medicines access equity strategic priority, and our Tiriti o Waitangi commitments. Te rautaki o Te Whaioranga also sets out to identify where changes to PHARMACs prioritisation process can be made to ensure equity for Māori, and to give effect to this.

[3] Vitz M et al, New Zealand may finally get funded access to diabetes drugs which reduce cardiovascular events and progression of kidney disease: an audit of proposed PHARMAC criteria compared with international guidelines NZMJ 2020;133(1523):76-86

Table 1: PHARMAC consideration of this proposal according to legal advice

Requirement	PHARMAC response
It does so in order to improve health outcomes for a disadvantaged group, particularly where it can be shown that the group is disadvantaged because of discriminatory treatment in the health system	There is widespread evidence that Māori and Pacific people are (very) disproportionately impacted by type 2 diabetes,[4] with disease burden 6-7 times that of non-Māori/non Pacific, and have the capacity to benefit from these treatments In addition, there is clear evidence that both population groups have been discriminated by the health system.[5],[6]
There is a real prospect that the inclusion of ethnicity in access criteria will address the disadvantage that is identified	PHARMAC has received consultation feedback from recognised experts, that the inclusion of an ethnicity criteria has the genuine potential to address the disadvantage (see Appendix Three). The gap between medicines need and uptake by ethnic groups persists, despite many years of discussion in the health sector, with good evidence that the apparent deficit in disease burden adjusted, age standardised dispensing for diabetes and renal disease does not appear to be closing[7]. This evidence suggests that the deficit is equally between access and persistence. As a result it is reasonable to conclude that activity to both increase access and maintain persistence in those who are initiated on treatment is required. We also received advice from recognised experts that Māori and Pacific people do not have equitable access to cardiovascular and renal risk assessment tests that would enable funded access under the original proposed criteria. The inclusion of the ethnicity component in the criteria can be expected to have the effect of partially removing this barrier and hence addressing the clear disparities.

[4] Yu D, Zhao Z, Osuagwu UL, et al Ethnic differences in mortality and hospital admission rates between Māori, Pacific, and European New Zealanders with type 2 diabetes between 1994 and 2018: a retrospective, population-based, longitudinal cohort study Lancet Glob Health 2020:S2214-109X(20)30412-5.

[5] Waitangi Tribunal (Te Rōpū Whakamana i te Tiriti o Waitangi). Hauora: Report on Stage One of the Health Services and Outcomes Kaupapa Inquiry. WAI 2575. Wellington: Department of Justice, 2019. https://waitangitribunal.govt.nz/inquiries/kaupapa-inquiries/health-services-and-outcomes-inquiry/

[6] Chin MH, King PT, Jones RG, Jones B, Ameratunga SN, Muramatsu N, Derrett S Lessons for achieving health equity comparing Aotearoa/New Zealand and the United States. Health Policy 2018;122(8):837-53 https://www ncbi nlm nih.gov/pmc/articles/PMC6561487/pdf/nihms-968322 pdf

[7] Metcalfe S, Beyene K, Urlich J, Jones R, Proffitt C, Harrison J, Andrews Ā. Te Wero tonu—the challenge continues: Māori access to medicines 2006/07-2012/13 update. N Z Med J. 2018;131:27-47; Auckland UniServices. Variation in medicines use by ethnicity: a comparison between 2006/7 and 2012/13. Final Report. Prepared for PHARMAC. Auckland: University of Auckland, 2018.

Requirement	PHARMAC response
It considers whether there may be reasonable (and similarly effective) alternative solutions that do not involve making distinctions on the basis of ethnicity	We had originally crafted the SA criteria with a view to being pro equity using purely clinical criteria Feedback received from recognised experts during consultation argued that these criteria were inadequate on the basis that Māori and Pacific people with type 2 diabetes have demonstrated differential cardiovascular and renal risk that cannot be fully captured in any other way Furthermore, we received feedback from recognised experts that Māori and Pacific people do not have equitable access to the cardiovascular and renal risk assessment tests that would enable funded access under the original proposed criteria. We considered the option of open listing these medicines, however this would not be possible within the available budget for pharmaceuticals. Furthermore, recent data suggests that open listing is ineffective in addressing inequities in access to medicines [8] Hence, to date, we cannot identify any other means in the Pharmaceutical Schedule for redressing entrenched access inequities, and where evidence is lacking from other programmes of sustained improvements that are rapid, sufficiently large and sufficiently timely to rapidly redress inequities. This approach recognises SA criteria are but one of many parts of a system that will be required to redress funded access inequities; alone as an action it is insufficient, but it is still necessary (where if each component was excluded because in itself it was insufficient, there would be no components; each plays a part and as such is necessary)
It considers whether any proposed use of ethnicity as a criterion is wider than necessary and whether, if ethnicity is a direct proxy for other causative factors, it may be more effective to address those factors directly	The development of the proposed SA criteria considered this matter. In this case the inclusion of ethnicity is a proxy for those people who have been the subject of complex systemic inequities and therefore are at a higher risk of complications from type 2 diabetes. This is independent of clinical variables that could instead be included We have been unable to identify any other factor which could be used to identify this group that could be workably applied as a criterion in clinical practice
It considers the position of those not able to access the pharmaceutical(s) in question, as well as any issues of over or under-inclusion (where people who do not need a measure benefit simply because they belong to the targeted group, while others	The development of the proposed SA criteria considered this matter It has been identified, for example, that South Asian ethnic groups are at higher risk of type 2 diabetes compared with other groups. However, in contrast to Māori and Pacific people, systemic barriers and outcomes disparities do not appear to be as significant (see , for example, a report from Counties Manukau DHB) People

[8] Chepulis L, Mayo C, Morison B, Keenan R, Lao C, Paul R, Lawrenson R. Metformin adherence in patients with type 2 diabetes and its association with glycated haemoglobin levels. J Prim Health Care 2020 (published online 5 November 2020).

Requirement	PHARMAC response
who may need it are denied the benefit because they belong to a group considered not to be disadvantaged)	who do not meet the proposed ethnicity criterion, but who would benefit most from treatment, would be captured through the other funding criteria used to define those at high risk of cardiovascular or renal complications of diabetes. The criteria are such that it is unlikely that significant over inclusion would occur because the criteria, coupled with the clinical judgment of prescribers, will ensure that only people who will benefit significantly from the treatment will receive it
It regularly monitors and evaluates the effectiveness of using ethnicity as an access criterion	As part of our medicines access equity monitoring work, and implementation activities specific to this transaction, we would monitor the uptake of these medicines by ethnicity, and by use of the various criteria If the proposed criterion 2 1 was not being utilised, and/or aspirations for medicines access equity were being met (based on a need adjusted uptake), we would look to remove this criterion at a future point in time.

We received consultation feedback on other matters related to the SA criteria, which we considered and further adjustments have been made to the proposed wording to clarify the intent. Further detail regarding feedback received is included in the consultation and consumer engagement section of this paper.

After considering all consultation feedback, including feedback and engagement after the closing date for consultation feedback, a number of changes were made to the proposed SA criteria. PHARMAC staff sought clinical advice on the updated criteria from our expert clinical advice network (including PTAC and our Diabetes, Cardiovascular and Nephrology Subcommittees). The final proposed SA criteria are as follows (with material additions to the SA criteria consulted on noted in **bold**, and deletions in ~~strikethrough~~):

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 being diagnosed with type 2 diabetes during childhood or as a young adult; or**
   - 2.5. Patient has diabetic kidney disease**; and
3. Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the regular use of ~~oral antidiabetic agents and/or insulin~~ **at least one blood-glucose lowering agent (e g , metformin, vildagliptin or insulin)** for at least ~~6~~**3** 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).
6. ~~Treatment must be used as an adjunct to oral antidiabetic therapy and/or insulin; and~~

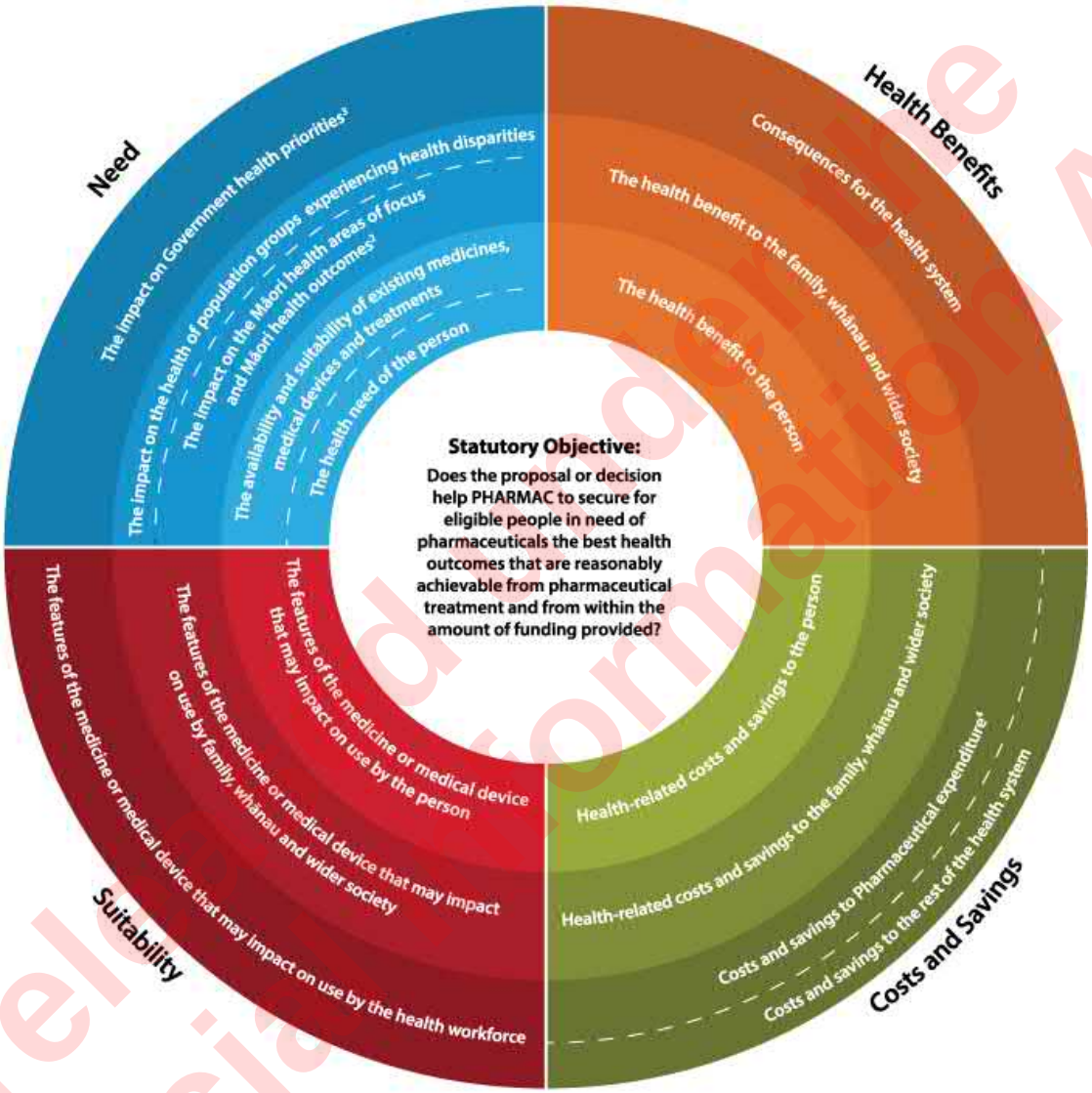
Note:

Criteria 2.1 – 2.5 describe 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.)

These criteria are intended to define the group of people who have type 2 diabetes, are at high risk of adverse cardiovascular (and renal) complications of type 2 diabetes, and for whom the first line treatment (usually metformin) is inadequate, while acknowledging the urgency for some patients to add one or other of these medicines to the initial treatment early Some consult feedback requested that the need for the use of metformin or some other antidiabetic agent in the first line should be waived for Māori and Pacific people. Our clinical advice indicates that metformin remains the standard of care in New Zealand for all people with type 2 diabetes, and that these criteria are broadly consistent with the patient group for whom there is clear evidence of benefit Furthermore, to remove the requirement for at least one prior treatment would likely result in an unacceptable impact to the CPB We also received feedback that access to HbA1c testing is a potential system barrier for Māori and Pacific people. While we acknowledge this may be the case to some extent, we also understand HbA1c testing to be fundamental to the management of type 2 diabetes. Furthermore, TestSafe data provided to PHARMAC by Counties Manukau DHB suggests that, for people with poor glycaemic control across the three Auckland metropolitan region DHBs, the proportion of people having HbA1c tests is numerically higher in Māori (87%) and Pacific people (88%) compared to European/other (82%) (unpublished data provided in confidence, proportions have not been adjusted for need, not a statistical comparison)

Factors for Consideration

This paper sets out PHARMAC staff's assessment of the proposal using the Factors for Consideration in the Operating Policies and Procedures Some Factors may be more or less relevant (or may not be relevant at all) depending on the type and nature of the decision being made and, therefore, judgement is always required The Board is not bound to accept this assessment of the proposal under the Factors for Consideration and may attribute different significance to each of the Factors from that attributed by PHARMAC staff.



Footnotes

[1] The person receiving the medicine or medical device must be an eligible person, as set out in the Health and Disability Services Eligibility Direction 2011 under Section 32 of the New Zealand Public Health and Disability Services Act 2000

[2] The current Māori health areas of focus are set out in PHARMAC's Te Whaioranga Strategy.

[3] Government health priorities are currently communicated to PHARMAC by the Minister of Health's Letter of Expectations.

[4] Pharmaceutical expenditure includes the impact on the Combined Pharmaceutical Budget (CPB) and / or DHB hospital budgets (as appropriate).

[5] Please note PHARMAC's Factors for Consideration schematic currently does not explicitly refer to the health needs of family, whānau and wider society, but this factor should be considered alongside those depicted in the schematic.

Factors for Consideration

Need

Background

Disease/illness

Type 2 diabetes is a disease where the body cannot regulate its blood sugar levels properly also called poor glycaemic control This is either because there isn't enough insulin being produced, or the body has become resistant to insulin. Type 2 diabetes usually develops in adults but it is becoming more common in children.

Type 2 diabetes is one of Aotearoa New Zealand's fastest growing long-term conditions. It is anticipated that this increasing burden of disease will have a significant impact on the health system, as more people will need to access primary health care services to manage their diabetes and primary, secondary and tertiary services to manage the complications of this condition.

Māori and Pacific people are particularly impacted by type 2 diabetes not only are these population groups more likely to have type 2 diabetes compared with Pākeha, but these population groups are more likely to develop complications from their diabetes, and at an earlier age South Asian people are also disproportionately affected by type 2 diabetes

Availability and suitability of existing treatments

A number of medicines are funded in Aotearoa New Zealand for the management of type 2 diabetes The funded medicines work by reducing blood sugar levels (i e , improving glycaemic control). In general, improving glycaemic control has been shown to improve the microvascular complications of diabetes (e.g., retinopathy, nephropathy, peripheral neuropathy) but not the macrovascular complications of diabetes (e g., heart failure, atherosclerotic cardiovascular disease). The most recent medicine for type 2 diabetes included in the Pharmaceutical Schedule was the DPP-4 inhibitor vildagliptin (with and without metformin) in October 2018.

We have received feedback from the health sector and from our clinical advisors that there is a compelling need to fund medicines that can help reduce the risk of cardiovascular and renal complications in people with type 2 diabetes at high risk of these complications Our clinical advice indicates that enabling access to either a SGLT 2 inhibitor or a GLP 1 agonist for high risk individuals would help to address this unmet need.

Impact on Māori health areas of focus and health outcomes

Matehuka diabetes has been identified by Māori as the second most important of the five Hauora Arotahi – Māori health areas of focus for PHARMAC Manawa ora heart health has been identified as the third. Both these hauora arotahi are considered relevant to this proposal, which aims to implement advances in the management and prevention of these conditions respectively

The Ministry of Health has reported that Māori are three times as likely as non-Māori to have type 2 diabetes, and are more likely to develop complications. Unfortunately, the incidence of type 2 diabetes is increasing in Māori under the age of 15 years

Health Benefit

Treatment under consideration

Health benefits to the person

Empagliflozin and empagliflozin with metformin

Empagliflozin is an SGLT 2 inhibitor. It is an oral tablet, usually taken once or twice daily. It would be available alone, and in a combination tablet with metformin Some medicines from the SGLT-2 inhibitor class, including empagliflozin, have been shown to reduce renal and cardiovascular complications including progression to renal failure and hospitalisation for heart failure, as well as major adverse cardiovascular events and cardiovascular death These medicines have also been shown to produce weight loss in people with type 2 diabetes. These benefits would be realised for some patients within a five year timeframe. These medicines do not work well in people with significant renal dysfunction Empagliflozin (with and without metformin) is generally well tolerated, but has been associated with clinically significant infections, hypoglycaemia and diabetic ketoacidosis. Funding is proposed for people with type 2 diabetes at high risk of cardiovascular and/or renal complications These people are at highest need, and the most likely to benefit from treatment with empagliflozin. We estimate that roughly 53,000 people would be eligible for and take up one of the new treatments under the proposed SA criteria, and that roughly 48,000 people would access this treatment (rather than a GLP 1 agonist). Of note, the SA criteria actively select for Māori and Pacific people and, based on clinical data from Auckland and Northland, we estimate that roughly 50% of eligible people would be Māori or Pacific people.

Dulaglutide

Dulaglutide is a GLP-1 agonist. It is an injection that is designed to be self-administered by the patient, once weekly. Medicines from the GLP 1 agonist class, including dulaglutide, have been shown to reduce renal and cardiovascular complications including progression to renal failure and a reduction in major adverse cardiovascular events. These benefits are unlikely to be realised within a five-year timeframe. These medicines work independently of renal function Medicines from this class have been shown to produce weight loss in people with and without diabetes, and are proactively marketed as a weight loss treatment, including in Aotearoa New Zealand. Dulaglutide is generally well tolerated, but has been associated with clinically significant diabetic ketoacidosis, in particular in people where concomitant insulin was rapidly reduced or discontinued. Funding is proposed for people with type 2 diabetes at high risk of cardiovascular and/or renal complications These people are at highest need, and the most likely to benefit from treatment with dulaglutide. We estimate that roughly 53,000 people would be eligible for and take up one of the new treatments under the proposed SA criteria and that in the region of 5,000 people per year would access this treatment (rather than the oral SGLT-2 inhibitor).

PTAC /Subcommittee View

In February 2019, PTAC considered that it was well-established that type 2 diabetes places a significant burden on the Aotearoa New Zealand Health system, and particularly Pacific people, Māori and South Asian populations. In these groups type 2 diabetes is more prevalent, more severe, and generally has an earlier onset of disease. Broadly speaking, the Committee considered that these medicines now had evidence to suggest benefit in cardiovascular and renal outcomes, and recommended that advice be sought from the Diabetes Subcommittee regarding the appropriate place of SGLT 2 inhibitors and GLP 1 agonists in the Aotearoa New Zealand treatment paradigm

In March 2019, the Diabetes Subcommittee of PTAC considered these agents and the request from PTAC regarding the appropriate place of SGLT 2 inhibitors and GLP 1 agonists in the Aotearoa New Zealand treatment paradigm

The Subcommittee recommended that antidiabetic agents be funded for the improvement of cardiovascular outcomes in type 2 diabetes patients with established CVD subject to the following SA criteria:

> Initial application from any medical 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 less than 64mmol/mol) despite maximum tolerated doses of oral antidiabetic agents and/or insulin for at least 6 months; and
> 3 Patient has 5 year absolute cardiovascular disease risk of 20% or greater according to a validated diabetes cardiovascular risk assessment calculator; and
> 4. Treatment is used to be used in conjunction with other measures to reduce cardiovascular risk in line with current standard of care; and
> 5. Treatment must be used as adjunct to oral antidiabetic therapy and/or insulin.

In May 2020, further advice was sought from the Diabetes Subcommittee regarding proposals received in response to the RFP, and the assumptions used in the evaluation of proposals. The Subcommittee considered that noted and reaffirmed previous clinical advice provided to PHARMAC, where it had been recorded that when an SGLT-2 inhibitor or GLP-1 agonist has been proven to offer cardiovascular benefit beyond the current standard of care, there can be considered to be a class effect within each class, i.e , the agents offer the same or similar benefit within the class. The Subcommittee considered that, based on currently available evidence, this class effect would apply to the SGLT 2 inhibitors dapagliflozin and empagliflozin (alone or as a combination product with metformin) The Subcommittee considered that this class effect would apply, based on currently available evidence, to the GLP 1 agonists dulaglutide and liraglutide The Subcommittee considered that, in the context of the current RFP, exenatide (twice daily formulation) did not meet the definition of a GLP-1 agonist with established evidence of cardiovascular benefit. The Subcommittee considered that, based on the evidence available, ertugliflozin was not considered to have established evidence of cardiovascular benefit. The record of this meeting is considered of a commercially sensitive nature and has not been published on the PHARMAC website. The record can be made provided to Board members on request.

Subsequent to the close of consultation, additional advice was sought via email from the Diabetes, Cardiovascular and Nephrology Subcommittees and PTAC regarding proposed amendments to the SA criteria based on the consultation feedback In general, this advice indicated that the final proposed wording is clinically appropriate. Some members considered the proposed wording to be significantly pro equity, while others considered the wording could go further A collation of the email responses received subsequent to the close of consultation is included as Appendix Four.

In general, the clinical advice received from PTAC and the Diabetes Subcommittee prior to 2019 regarding these medicines was that the evidence of clinical efficacy reported was of moderate quality and strength for a benefit in glycaemic control. However, the lack of long term data on efficacy and safety as well as the use of surrogate clinical endpoints were noted as issues Uncertainty surrounding the place of these new agents in the diabetes treatment paradigm was also noted. Overall, PTAC considered that these medicines (SGLT 2 inhibitors, GLP 1 agonists and DPP 4 inhibitors), were generally similar in terms of reducing HbA1c by approximately 0.5% to 1% and that there was a lack of evidence supporting clinically significant benefits other than decreased HbA1c.

More information, including links to the records of PTAC and the relevant Subcommittee meetings, which include a detailed analysis of the clinical trial evidence about health benefits, can be found in the Application Tracker record for SGLT 2 inhibitors with proven CV benefit, and GLP 1 agonists with proven CV benefit.

Advisor Conflicts of Interest

All declared conflict(s) of interest for any clinical advisors who contributed to the above advice, and actions taken to manage the conflict(s), are recorded in the relevant minutes A report of potentially relevant conflicts is provided in Appendix Four. The Board may wish to take this into account when considering the advice received.

Suitability

For all medicines in this proposal, stat (all at once) dispensing would be applied to enable three months of treatment to be collected in one pharmacy visit. This is likely to be more suitable for patients than month by month dispensing.

Empagliflozin and empagliflozin with metformin

Empagliflozin with or without metformin is a tablet generally taken once or twice daily.

For people who are already taking metformin this could mean a reduction in the number of tablets that need to be taken each day. We have received feedback that a combination tablet has the potential to improve adherence and persistence with medicines. This suitability element was considered preferable to other options by the Diabetes Subcommittee and the RFP Evaluation Committee. Feedback was received through our consultation that the combination with metformin is a useful feature. We note that no other SGLT 2 inhibitor included in the proposals in the response to the RFP included the option of a combination product with metformin.

The tablets are supplied in 30-day pack sizes, which aligns with the most common anticipated dispensed quantities.

Dulaglutide

Dulaglutide is presented in a pre-filled syringe device and is generally given as a once weekly subcutaneous injection The once weekly frequency of injection was considered preferable to other options by the Diabetes Subcommittee and the RFP Evaluation Committee. The pre filled pen device is designed to facilitate self administration, without the assistance of a health professional Feedback was received through our consultation that the once weekly dosing schedule makes dulaglutide a preferable GLP 1 agonist option. We note that all other GLP 1 agonists included in the proposals in the response to the RFP were for more frequent injections (i.e., once or twice daily).

The injections are supplied in a four week pack size, which aligns with the most common dispensed quantities for medicines that are taken once weekly Dulaglutide (like all other GLP 1 agonists included in the proposals) needs to be stored in the fridge, but can be kept for up to 14 days at room temperature.

Dulaglutide has not been approved by Medsafe. An application was submitted by the supplier in August 2020 (using an abridged pathway) We would only list this pharmaceutical in the Pharmaceutical Schedule after approval by Medsafe We consider the earliest possible date for this would be 1 June 2021. We would continue to communicate with the supplier and Medsafe to monitor the progress of this application

Costs and Savings

Health related costs and savings to the person

The Diabetes Subcommittee has advised us that a SGLT 2 inhibitor or GLP-1 agonist would be used in addition to (rather than instead of) currently prescribed anti-diabetes medicines. This means that for patients who are prescribed an additional medicine for type 2 diabetes as a result of this proposal, an estimated four additional prescription co payments per person per year would apply.

For those patients who are already taking metformin and move to the combination of empagliflozin with metformin there would be no incremental difference in co-payments

We consider that given the high risk nature of the targeted population, some people may reach the threshold for the Ministry of Health prescription subsidy scheme, in which case there would be no additional co-payment costs for those individuals, their partners and their dependent children.

We consider there may be some people who change from another funded treatment to empagliflozin or dulaglutide, in which any co-payment cost would be offset.

For those patients requiring an additional visit to a health care professional in order to be assessed for eligibility for one of the new funded medicines, an additional visit fee would be incurred. We consider that for the majority of patients this would be completed as part of routine healthcare for their condition.

Health related costs and savings to the family, whānau and wider community

No health-related costs to the family, whānau or wider community are anticipated as a result of this proposal.

The delay or avoidance of complications of diabetes is likely to result in some health related savings to family, whānau and the wider community. For example, a delayed time to renal replacement therapy could mean a reduction in travel costs to and from a dialysis centre. Another example is avoidance of hospitalisation for heart failure whereby family and whānau could avoid the cost of accommodation nearby the hospital. These savings are anticipated, but have not been quantified

Cost and savings to Pharmaceutical expenditure

Overall to the CPB, this proposal involves a combination of new investments totalling Withheld Withhel versus the status quo

<u>Empagliflozin (with and without metformin)</u>

This part of the proposal represents a new investment with a total net cost of Withheld under to the CPB (versus status quo, 5 year NPV, 8% discount rate).

Dulaglutide

To the CPB, this part of the proposal involves a new investment with a total net cost of Withheld Withhel to the CPB (versus status quo, 5 year NPV, 8% discount rate)

Costs and savings to the rest of the health system

There are number of costs and savings that would be likely to occur as a result of this proposal These range from the potential cost of an extra visit to a health care professional for the initiation of a new treatment for some patients, and increased distribution costs from the new medicines, to the savings from reduced dispensing of metformin to avoided heart failure hospitalisation and renal replacement therapy. Some of the reduction in heart failure hospitalisation and renal replacement attributable to empagliflozin is anticipated to occur within a five year time horizon (the remainder of the benefit of empagliflozin and dulaglutide would be realised over a longer term). Taking these into consideration, we estimate that this proposal would represent an overall sector saving of $27 2 million compared to status quo (5 year NPV, 8% discount rate). These savings would accrue to DHBs but not the CPB.

Budget impact assessment (BIA) on the CPB

A summary of PHARMAC staff's BIA of the overall proposal and of individual BIAs for each pharmaceutical included in the proposal is provided in the executive summary above.

The analysis makes the following key assumptions (informed by data and clinical advice);

- the total eligible patient population under the originally proposed SA criteria is roughly 60,000, and of these 48,000 (80%) was likely to be the maximum uptake
- taking into account the changes made to the criteria in response to consultation feedback, total patient uptake would be 110% of previously forecast i e., 52,800 people
- of this 52,800, 90% would start a SGLT 2 inhibitor, 10% would start a GLP 1 agonist
- uptake would be relatively rapid with 43% of people commencing treatment in the first 6-months, increasing to 67% by the end of year 1 and 100% by the end of year 2, based on what has been observed for vildagliptin
- for people prescribed empagliflozin with metformin, the CPB cost of metformin as a single agent would be directly offset.
- no additional pharmaceutical costs are offset by this proposal.

We consider it difficult to precisely estimate the change in uptake that would occur as a result of the amended SA criteria proposed after consideration of consultation feedback. As the original criteria were designed to target those at high risk of cardiovascular or renal complications of type 2 diabetes, and the updated criteria are refined to meet this same objective, it is possible that the uptake would not change. However, we have applied an estimate of 10% increase overall, on the basis that more people may be considered to be eligible under the updated criteria in comparison to the original criteria

We consider that the proposal may lead to additional offsets for the CPB through reduction in use of, or a reduction in the dose of, currently funded treatments for type 2 diabetes This would result in a reduced cost to the CPB. However, on the basis of the clinical advice received from the Diabetes Subcommittee that SGLT 2 inhibitors and GLP 1 agonists would be used in addition to current treatments, this has not been included as an assumption in the budget impact analysis. We consider this to be a conservative approach.

It is important to note that, based on our current budget path, even with transfer of funds from 2020/21 to 2021/22 via the Discretionary Pharmaceutical Fund (DPF), this proposal would see us overspend our current outyear budget pathway Table 2 below describes the current CPB position, and the net impact of this proposal, together with an indicative headroom should our 2021 budget bid be accepted We propose that this overspend would be managed through the budget bid process, as well as transfer of any remaining funds from the 2020/21 financial year via the DPF. This would leave additional headroom for further investments of CPB funds in outyears

Table 2: Forecasted spend/(save) to achieve budget under different scenarios ($m)

	2020/21	2021/22	2022/23	2023/24	2024/25
Spend/(save) to achieve target current	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)				
Net cost proposal	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)				
Spend/(save) to achieve target including proposal	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)				
Budget 2021 CPB bid		40	45	55	60
Spend/(save) to achieve target assuming budget bid approved	Withheld under section 9(2)(b)(ii), 9(2)(ba)(i) and 9(2)(j)				

Note that PHARMAC staff have conducted a sensitivity analysis of our assumptions relating to speed of uptake and mix of use for the SGLT 2 inhibitor and GLP 1 agonist. We are comfortable that, although the budget would be tight in 2021/22, we would have sufficient funds available to manage an unexpected increase via our DPFs, assuming our budget bid is successful

Consideration of alternative option of open listing an SGLT-2 inhibitor

During the development of this proposal, including in our consideration of consultation feedback, we contemplated an alternative option of funding only a SGLT 2 inhibitor without restriction by SA criteria (i.e., open listed), noting that a proposal for open listing of an SGLT 2 inhibitor sits very close to this proposal on the Options for Investment priority list (see Board agenda item 9 2 Prioritisation report) While initially considered to be pro-equity some feedback we have received during our engagement with stakeholders has indicated that open listing of an SGLT-2 inhibitor would be a passive approach to medicines access equity, and may not achieve the desired outcome of differential access for Māori and Pacific people

We have determined that funding two new diabetes treatments remains the preferred funding proposal, noting the following key points:

- open listing of an SGLT 2 would not be achievable within the current CPB budget pathway
    - we note that this option has a highly uncertain budget impact, based on significant uncertainty in uptake numbers A base case estimate for this budgetary impact to the CPB is around Withheld 5-year NPV (slightly less than the proposal before the Board for a decision), however expenditure could reasonably be expected to reach a net cost to the CPB of Withheld under (gross cost of Withheld under), with an overall DHB cost of $167 million once distribution costs have been factored in (all figures are versus status quo, 5-year NPV, 8% discount rate, assuming a 1 December 2020 list date);
    - the preferred RFP bid for open listing (from a budgetary impact perspective) was dapagliflozin, but it did not include a proposal for a fixed-dose combination product with metformin. According to our clinical advice and consultation feedback, this would be a less suitable option with respect to adherence and persistence, and would increase the number of prescriptions (and associated charges) for those patients who would

otherwise use the combination tablet. To open list empagliflozin with and without metformin at the price proposed via the RFP is estimated to have a base case net cost to the CPB of Withheld under [illegible] versus status quo (5 year NPV, 8% discount rate, assuming a 1 December 2020 list date);

- an open listing scenario could result in access to these medicines for an estimated 250,000 people, of whom roughly 195,000 would not be expected (based on clinical trials to date), to derive substantial clinical benefit beyond a reduction in weight and a modest improvement in glycaemic control compared with status quo;
- other health sector costs or savings are significantly uncertain and, for ~195,000 extra patients that would gain funded access via an open listing, could range from the cost of one additional visit to the GP per patient per year, to a saving of one additional visit per patient per year (assumed to be $80 per visit).

Cost-Effectiveness

The overall cost effectiveness of this proposal is estimated to be in the range of Withheld [illegible] (possible range Withheld [illegible]) QALYs per million dollars.

Empagliflozin (with and without metformin)

As a standalone proposal, the cost-effectiveness of a SGLT-2 inhibitor (empagliflozin) for patients with high CVD risk as described in the proposed SA criteria is estimated to be likely to be between Withheld [illegible] QALYs per $1 million net health sector costs invested. The cost effectiveness range reflects likely variation in the rate of death, rate of progression to macroalbuminuria and rate heart failure hospitalisation as well as variation in non-intervention treatment costs and a delay in progression to insulin.

Technology Assessment Report (TAR) 382 – "SGLT-2 inhibitors for type 2 diabetes with high CVD risk" can be provided upon request.

Dulaglutide

As a standalone proposal, the cost-effectiveness of a GLP 1 receptor agonist (dulaglutide) for patients with high CVD risk as described in the proposed SA criteria is estimated to be likely to be between Withhel [illegible] QALYs per $1 million net health sector costs invested The cost effectiveness range reflects likely variation in the rate of progression to macroalbuminuria as well as variation in non intervention treatment costs and a delay in progression to insulin.

Technology Assessment Report (TAR) 383 "GLPs for type 2 diabetes with high CVD disease risk" can be provided upon request.

This cost utility analysis (CUA) has not been updated subsequent to the changes made to the SA criteria following consideration of consultation feedback This is because the updated SA criteria are designed to meet the original intent of targeting treatment to a high-risk population who would likely derive the benefits at the same cost as modelled in our original assessment. It is indeed possible that some individuals would access treatment under the updated criteria who would not fit the intended group and this could in turn reduce the overall cost-effectiveness slightly. This however has not been quantified.

Consultation and Consumer Engagement

Consumer and public engagement

Consumer engagement prior to the development of this proposal was via the national consumer advocacy group Diabetes New Zealand. We met with representatives of this group on a number of occasions to discuss the proposed RFP
We also released a proactive media statement at the time of consultation We included Māori and Pacific media in this release.

PHARMAC's Consumer Advisory Committee (CAC) met on 6 November 2020 and we took this opportunity to share with the Committee a summary of the consultation process to date and our planned approach to responding to the feedback

Consultation

Section 49(a) of the New Zealand Public Health and Disability Act 2000 (the Act) requires PHARMAC to consult, when it considers appropriate to do so, on matters that relate to the management of pharmaceutical expenditure with any sections of the public, groups or individuals that, in the view of PHARMAC, may be affected by decisions on those matters

Accordingly, a consultation letter was circulated on 9 September 2020 to all relevant consumer advocacy groups, health care professional organisations and societies (including to our Māori and Pacific health care professional networks), and other parties that, in the view of PHARMAC, have an interest or stake in the recommendations contained in this paper

The consultation letter, the distribution list, a detailed summary and all responses received by 8 October 2020 are attached as Appendix Two. We received feedback from around 60 different individuals, clinician and patient organisations. Respondents included the Royal Australasian College of Physicians (RACP), Royal New Zealand College of General Practitioners (RNCGP), Te Rōpū Whakakaupapa Urutā (Urutā)[9] and Te Ohu Rata o Aotearoa Māori Medical Practitioners (Te ORA) among many others. The feedback received was rich and varied and, while generally very supportive of the funding of the two new medicines, raised some important considerations for PHARMAC relating to our processes for meaningfully considering health and medicines access equity in our funding decisions.

After early consideration of written consultation feedback we conducted targeted engagement with a number of stakeholder groups to further understand the feedback provided. We engaged with Urutā, Diabetes Foundation Aotearoa and the Pan Pacific Nurses Association. We also offered to meet with the RACP and Te ORA These two groups indicated that our engagement with Urutā would likely represent their views as well. We also attended a cross-disciplinary meeting with representation from diabetes, renal, cardiology clinical groups as well as Urutā, where equity of access to these medicines was discussed in detail

Following careful consideration of the feedback received, further engagement with the sector and clinical advice received via email, PHARMAC staff have updated the proposed SA criteria as described above. We consider that the updated SA criteria reflect the original intent of the proposal, while responding as much as possible to the, sometimes contradictory, feedback received. Therefore, PHARMAC staff do not consider that further public consultation is necessary on the revised criteria. Key correspondence from the period after consultation closed is included in Appendix Two

[9] Te Rōpū Whakakaupapa Urutā is made up of most of the nation's leading Māori medical and health experts including Primary Care Specialists, Public Health experts, Public Health Physicians, Māori Nurses and iwi leaders. Founded in response to the COVID-19 pandemic, the group is now focussing on health inequities for Māori and Māori health aspirations more broadly.

A summary of what we believe are the significant matters raised in written responses is provided in Table 3 below

Table 3: Summary of consultation feedback and PHARMAC response

Theme	PHARMAC Response
General topics	
Feedback from consumers, consumer representative groups, clinicians and clinician representative groups was, in general, strongly supportive of the funding of SGLT-2 inhibitor and/or GLP 1 agonist The following sub-themes were identified from some, but not all, respondents: • current treatments are inadequate • proposed SA criteria are broadly aligned with international treatment recommendations	We are encouraged that the funding of empagliflozin and dulaglutide has, in general terms, been supported by the vast majority of respondents to this consultation.
A number of health care professional groups and individual clinicians considered this proposal would help address health inequities in Aotearoa New Zealand, including for Māori and Pacific people	Supporting the reduction of health inequities in Aotearoa New Zealand is a priority for PHARMAC. Notwithstanding other important feedback received on the topic of health equity, we are pleased that the funding of empagliflozin and dulaglutide is viewed as a positive step towards improving this Following careful consideration of consultation feedback, we made changes to the SA criteria with the intentional view to further enhance the health equity focus of this proposal
Two groups noted they would like to see access widened/SA criteria removed in future	Unfortunately, this has not been achievable through the current RFP process within the current budget for pharmaceuticals We intend to actively monitor uptake, with a view to identifying opportunities to enhance medicines access equity. We anticipate that prices for these classes of medicines will reduce over time, in which case we would hope to be able to remove SA criteria altogether.
Two groups considered that PHARMAC should report on the regulatory approval progress of dulaglutide	Regulatory approval is the responsibility of Medsafe, and the status of applications are publicised on the Medsafe website We regularly engage with Medsafe and would continue to communicate with Medsafe to monitor the progress of the regulatory application

Theme	PHARMAC Response
Two groups considered the consultation process too short to allow PHARMAC to meaningfully consider the feedback received	We are grateful for the time that respondents took in responding to our consultation, which was conducted under timeframes consistent with our usual processes. All feedback has been carefully considered and provided in full to the Board when making its decision. Given the complexity of the feedback received, we have taken more time than anticipated to consider it
One group considered that dulaglutide has a less convincing CV evidence base compared with the SGLT 2 inhibitors	Our clinical advice has indicated that dulaglutide has established evidence of cardiovascular benefit, in line with other GLP 1 agonists. We note that the label for dulaglutide has recently been updated in international jurisdictions to include a cardiovascular indication We welcome the opportunity to approve the funding of both a SGLT 2 inhibitor and a GLP 1 agonist, and we understand the different mechanisms of action may be more suitable or less effective for different individuals based on their clinical circumstances.
Two individuals (a pharmacist and a consumer) were not supportive, on the basis that they consider funding should be used elsewhere, e.g , to maintain access to funded innovator brands or health care professional and/or patient education instead	PHARMAC uses a prioritisation approach to determine what to use our fixed budget for and this proposal ranks high on our options for investment list for the Aotearoa New Zealand budget for pharmaceuticals
Special Authority criteria changes (see also Health equity – Special Authority criteria)	
A number of clinician groups and individuals requested that the criterion related to maximum tolerated dose of anti-diabetic treatments be clarified to only require metformin as a prior treatment	We have considered this feedback and sought additional clinical advice The proposed SA criteria have subsequently been amended to clarify that at least one prior anti diabetes medicine (e.g., metformin or insulin) should have failed the patient prior to initiation of treatment with empagliflozin or dulaglutide. We have also reduced the time requirement for discovering whether first line treatment is unsuccessful from 6 months to 3 months
A number of clinician groups were supportive of, or recommended that, other practitioners (e.g., nurse practitioners, pharmacist prescribers), including those in primary care, be allowed to apply for SA	The proposal is to allow any relevant practitioner (which includes nurse practitioners and pharmacist prescribers) to apply for a SA for these medicines. Based on the feedback we received, we would ensure there is clear communication on this point as part of the implementation of this proposal See also the specific response to comments made about nurse prescribers below

Theme	PHARMAC Response
Three groups asked that the SA criteria be removed to enable access to all people who would want treatment with one of these new medicines	The use of SA criteria is one tool we use to help manage Aotearoa New Zealand's budget for spending on pharmaceuticals by targeting funded access to those who would benefit most from treatment We anticipate that prices for these classes of medicines will reduce over time, in which case we would hope to be able to remove the SA criteria altogether.
Health equity – Special Authority criteria	
A number of groups, including Urutā, Te ORA RACP, considered the existence of SA criteria will reduce the ability of Māori and other high-risk populations to access these treatments, and called for the removal of these criteria	We had hoped to be able to list at least one of these new medicines without SA criteria Unfortunately, this has not been achievable through the current RFP process within the current budget for pharmaceuticals. Instead we worked extensively with our clinical advisors and external clinician groups to develop SA criteria that are considered to be pro equity (Vitz et al). Following careful consideration of consultation feedback we have amended the SA criteria to ensure these medicines are better targeted to the intended high risk population group. We are aware that people of South Asian ethnicities are at a higher risk of diabetes and its complications compared to other groups However, the evidence of disparities in access to health care is clear for Māori and Pacific people. The SA include other criteria to identify those with high risk disease that would be met by other groups. We would work to support the sector with implementation activities with the express purpose of supporting equitable access to these medicines.
Some clinicians have considered (in the presence of ethnicity criteria for patients who are Māori and any Pacific ethnicities) that South Asian ethnicities (Indian, etc) should be included in any ethnic based criteria	The available evidence in relation to medicine access by Indian ethnicity is from the Auckland region, where Indian people have access to diabetes medicines and cardiovascular triple therapy at rates similar to NZ Europeans and access rates much higher than Māori and Pacific peoples.[10] This suggests that they are not (generally) a population that experiences inequities in medicine access like Māori and Pacific and they are able to access medicines at higher rates for CVD and diabetes. At this stage it would appear, under the proposed criteria, they would get good access.

[10] Wing Cheuk Chan. Diabetes care in the context of SGLT-2 inhibitor and GLP-1 agonists: How many people in Auckland metro are meeting clinical criteria in the context of multi-morbidities? Population Health Team, Counties Manukau District Health Board, 21 November 2020. Slides 15-17, 20-24.

Chan WC, Lee M (AW), Papaconstantinou D Understanding the heterogeneity of the diabetes population in Metro Auckland in 2018 Auckland: Counties Manukau Health, 2020

Chan WC, Papaconstantinou D. The need for better focus on primary and secondary prevention of cardiovascular disease. Auckland: Counties Manukau Health, 2020. pages 3, 15-17.

Theme	PHARMAC Response
	Indian ethnicity is included as part of the 5 year CV risk calculations[11] (as is Māori and Pacific ethnicities, albeit the calculations do not account for their poorer access to health services)
Three groups, including the New Zealand Child and Youth Clinical Network – Diabetes, considered the proposed SA criteria would not permit access to youth with type 2 diabetes – a group in which Pacific, South Asian and Māori are over-represented, and for whom lifetime (but not five year) cardiovascular and renal complication risk is high – and called for the addition of a criterion based on age	We have considered this feedback and sought additional clinical advice. We have amended the SA criteria to enable access to people diagnosed with type 2 diabetes in childhood or as young adults and who therefore have a high lifetime risk of cardiovascular complications from type 2 diabetes, but for whom a 5 year risk calculation may be inappropriate.
A number of groups considered that there is a need for dual funding of SGLT-2 inhibitors together with GLP 1 agonists, including to reduce inequities in access. They considered the rationale for excluding this was not clear from the proposal	Concomitant use of a SGLT 2 inhibitor and GLP-1 agonist was outside of the scope of the RFP, and PHARMAC has not had a funding application for the combined use of these two medicines so we have not been able to fully assess the evidence for or take appropriately considered clinical advice on such use PHARMAC staff intend to initiate a funding application for the combined use, which would be assessed using our usual funding application process
Two groups considered that Māori and Pacific people living with type 2 diabetes should have a direct pathway to access these medicines e g , via an equity criterion	Following careful consideration of consultation feedback we have amended the proposed SA criteria to clarify that Māori and Pacific people who also meet certain other criteria would have access to these medicines. This recognises the heightened risk of cardiovascular and renal outcomes in these ethnic groups.
Two groups noted that the SA criteria rely on screening and testing (e g , HbA1c, ACR, CV risk assessment) which they consider to be inequitably delivered so would increase and entrench inequity for Māori and Pacific people	PHARMAC acknowledges that significant health inequities exist in Aotearoa New Zealand, these are unacceptable, and that PHARMAC is a part of a system that has perpetuated these inequities. We consider that the tests included in the SA are in line with quality care that should be available to all people living in Aotearoa New Zealand, particularly those at high risk of complications from type 2 diabetes. PHARMAC does not have a direct role in the provision of screening and testing We have amended the SA criteria to clarify that Māori and Pacific people meeting certain other criteria would have access to these medicines given the heightened risk of cardiovascular and renal outcomes in these ethnic groups. We note that the criteria would still require that all people accessing these medicines have an HbA1c test. Our advice indicated that this would be appropriate clinical

[11] Pylypchuk R, Wells S, Kerr A, Poppe K, Riddell T, Harwood M, Exeter D, Mehta S, Grey C, Wu BP, Metcalf P, Warren J, Harrison J, Marshall R, Jackson R. Cardiovascular disease risk prediction equations in 400 000 primary care patients in New Zealand: a derivation and validation study. Lancet. 2018;391(10133):1897-907.

Theme	PHARMAC Response
	management for people with type 2 diabetes, including when considering a person for their clinical appropriateness for these treatments We are also aware of local data suggesting that amongst people with poor glycaemic control, access to HbA1c is relatively equitable
Two respondents, including Diabetes New Zealand, considered that equity in prescribing will be improved by the proposed SA criteria	Noted Following careful consideration of consultation feedback, we have made further changes with the intentional aim of further enhancing the health equity focus of this proposal
Health equity PHARMAC processes	
A number of respondents considered the lengthy time from evidence to the treatments being funded is not ideal, particularly given the significant health inequities in type 2 diabetes in Aotearoa New Zealand	PHARMAC staff acknowledge the need for medicines to further improve standards of care for high risk type 2 diabetes in Aotearoa New Zealand and we are pleased to be proposing to fund empagliflozin (with and without metformin) from 1 February 2021, and dulaglutide as soon as is practical.
Urutā, Te ORA and the RACP considered that equity members should be added to PTAC and other clinical advisory groups, and that PHARMAC should review its process for equity in funding decisions	PHARMAC staff acknowledges that significant health inequities exist in Aotearoa New Zealand, these are unacceptable, and that PHARMAC is a part of a system that has perpetuated these inequities We are working to enhance PHARMAC's equity capabilities, including our processes related to funding decisions and when seeking clinical advice. We have been actively focussed on improving our equity capability on clinical advisory groups particularly in the last recruitment round and we have a plan to further address this over the coming year We consider that some of the feedback received will be valuable not only in informing the decision on this proposal, but in informing our ongoing work in this area.
A number of groups noted the importance of monitoring uptake by ethnicity and region, using a clear and strong equity framework	PHARMAC staff intend to actively monitor and evaluate uptake of these medicines with a view to identifying opportunities to enhance medicines access equity We would report on this monitoring as part of our medicines access equity work, and specifically to support the ongoing implementation of these new medicines This will also be delivered as a priority through our responsible use of pharmaceuticals provider that has a strong focus on access equity and will be focussed on supporting equitable use of diabetes medicines as part of their work programme. We intend to work with the sector, including Māori health experts, to design our approach to this work and analysis of the results

Theme	PHARMAC Response
A number of groups considered that PHARMAC should proactively engage with communities when developing funding proposals and implementation plans	PHARMAC is aware that the opportunities for consumers and communities to input into our funding decisions is not clear and that there is room for improvement. We are open to considering different ways we could do this, and in the first instance are working with our Consumer Advisory Committee (CAC) to seek its feedback on funding proposals earlier in the decision making process We will also be consulting soon on proposed changes to the PTAC and CAC terms of reference which propose the inclusion of consumer representatives on PTAC.
Implementation	
The majority of respondents noted it would be important to educate prescribers, including in primary care about the availability and appropriate use of the new medicines	PHARMAC staff acknowledge the need for education for healthcare professionals on the initiation and continued support of use of these treatments. PHARMAC staff are aware that the type 2 diabetes guidelines are currently being updated by NZSSD and the MoH and we consider that these will help provide clear guidance of the place of these medicines in treatments PHARMAC's responsible use service provider, Matui, is focused on developing tools and resources to support the use of these, and other, treatments for type 2 diabetes and has already begun delivering these. These resources will have a major focus on promoting equity of access to these, and other, treatments
A number of groups considered that PHARMAC should partner with Māori experts and other expert groups to develop and implement a pro-active plan to support equitable prescribing	PHARMAC welcomes the opportunity to engage with experts to help support equitable prescribing of and access to these treatments PHARMAC's Implementation and Access Equity programmes will continue to look for opportunities to undertake work to support equitable access to funded treatments in key health areas.
A number of respondents suggested that proactive identification and recall of eligible patients using clinical practice tools and systems will enhance access	Noted. We intend to encourage healthcare professionals to proactively identify their patients who would benefit most from treatment as part of our implementation support activities. PHARMAC staff would actively monitor the uptake of these treatments and share outcomes by ethnicity and DHB region

Theme	PHARMAC Response
A number of groups suggested that patient-facing resources and support, specifically be designed for and co developed by Pacific, South Asian and Māori (including in language) to help uptake and adherence	PHARMAC staff would work with the suppliers of these treatments to ensure that meaningful patient information is co created with the people who would be eligible for funded access to these treatments We would ensure that these materials are freely available online and in downloadable format from sites that have a focus on supporting consumers, e.g., Health Navigator
Two groups suggested that media advertising/direct marketing, including targeted to Māori and Pacific people may be useful to support uptake	We would engage with the Ministry of Health and the Health Promotion Agency to identify any opportunities to work together on promoting diabetes awareness campaigns.
A number of groups offered their support for implementation activities including: • research uptake and the impact of the proposed SA criteria on medicines access equity • Healthcare professional education • community-based education	PHARMAC welcomes the support of sector partners The successful implementation of this proposal, if approved, will be important in enhancing health outcomes and health equity in Aotearoa New Zealand.
Suitability	
Respondents considered that dulaglutide is a suitable option of GLP-1 agonist (weekly dosing, retracting needle)	Noted.
Respondents considered that a fixed dose combination of SGLT 2 inhibitor with metformin is suitable (e.g., no additional co-payment, no additional tablet to take)	Noted.
Sector costs	
One DHB noted that there would be a cost to the sector to educate people on self-administration of dulaglutide	PHARMAC has considered costs and savings to the sector as a result of this proposal, including the cost of initiating injectable treatments. We consider that the proposal overall represents a good investment of DHB funds.
One pharmacist considered that administration of the SA criteria will be an added burden to pharmacists	PHARMAC has considered costs and savings to the sector as a result of this proposal We note that the proposed SA is valid without further renewal which should minimise the administrative burden to pharmacists.

Theme	PHARMAC Response
Request for funding of other pharmaceuticals	
Two respondents made a request to also fund CGM/Freestyle Libre for T1DM	The scope of the RFP was for SGLT 2 inhibitors, GLP-1 agonists and DPP-4 inhibitors We are considering applications for the funding of blood glucose monitoring technologies, including for type 1 diabetes Progress of these funding applications can be noted via our Application tracker: • Freestyle Libre • Continuous Glucose Monitors
Two groups made a request to fund extended release metformin	Extended-release metformin was not within scope of the RFP PHARMAC has received advice that this would be a suitable option for people with type 2 diabetes, and we have included this medicine in our 2020/21 annual invitation to tender
One group called to reduce funding for, what they considered to be, less effective medicines (e.g., other type 2 diabetes medicines, including vildagliptin), and to restrict access to insulin in order to enable open access to SGLT 2 inhibitor and GLP-1 agonist	A change to the funding arrangements for other medicines on the Pharmaceutical Schedule is not in the scope of this proposal We seek regular advice from our clinical advisors on ongoing maintenance of the listings in the Schedule.
One group requested to include pre-diabetes in scope of SA criteria	We have not received an application for the funding of a SGLT-2 inhibitor or a GLP 1 agonist for the treatment of pre-diabetes. We would welcome a funding application for the use of one or more of these medicines in the treatment of pre-diabetes
Some respondents requested to include heart failure without diabetes in scope of SA criteria	We have not received an application for the funding of a SGLT-2 inhibitor or a GLP-1 agonist for the treatment of heart failure without diabetes. We would welcome a funding application for the use of one or more of these medicines in the treatment of heart failure without diabetes
One respondent requested the inclusion of weight loss indication within scope of SA criteria (irrespective of cardiovascular or renal disease)	We have not received an application for the funding of a SGLT-2 inhibitor or a GLP-1 agonist to produce weight loss We would welcome a funding application for the use of one or more of these medicines for weight loss.
Request for a second SGLT-2 inhibitor to be funded	The RFP sought proposals for the sole supply of a SGLT 2 inhibitor Therefore, the funding of a second SGLT-2 inhibitor would not be possible for at least three years if this proposal is approved.
One respondent suggested funding of medicine adherence/persistence support technology (e g , apps) alongside the medicines for type 2 diabetes	PHARMAC staff are supportive of implementation activities that will support medicines access equity, including medicine adherence and persistence The funding of technologies to support medicine adherence and persistence is currently considered to be outside of the scope of CPB.

Theme	PHARMAC Response
Sector change requests	
A number of respondents called for overall sector-wide improvement in quality of care for Māori and Pacific and other people experiencing inequitable outcomes from type 2 diabetes	PHARMAC acknowledges that significant health inequities exist in Aotearoa New Zealand, these are unacceptable, and that PHARMAC is a part of a system that has perpetuated these inequities We have shared this feedback with the Ministry of Health and we will continue to work with our sector partners to enhance PHARMAC's equity capabilities
A pharmacist representative group considered that increasing the availability of prescribing and clinical pharmacists in primary care across Aotearoa New Zealand would help in enhancing medicines access	Noted We have shared this feedback with the Ministry of Health who is responsible for health workforce development issues in New Zealand.
A number clinician groups, including nursing groups, recommend nurse prescribers be able to prescribe and apply for Special Authority	The proposal is to allow any relevant practitioner (which includes nurse practitioners and pharmacist prescribers) to apply for a SA for these medicines. We are aware of ongoing conversations to include empagliflozin (with and without metformin) and dulaglutide within the scope of practice for nurse prescribers The ability of additional health care professionals to apply for SA criteria is managed by the Ministry of Health, and we have shared this feedback with them
A number of respondents called for subsidy of these medicines (interpreted as removing the patient co-payment), and/or for visits with prescribers and other relevant health care professionals	The policies for co payment and patient charges for health care professional visits and dispensing of pharmaceuticals sit with the Ministry of Health, and we have shared this feedback with them

Legal Advice

Where necessary, management will obtain legal advice on issues such as whether any proposal is consistent with PHARMAC's legislative and public law obligations, including those that may have specific relevance to the particular proposal, e.g., human rights implications of a proposal. If the Board considers that further legal advice is required on any issue, this should be communicated to management in advance of the Board meeting Management will then obtain the required advice.

Legal Advisors' View

Confidential and Legally Privileged Advice from PHARMAC's legal advisors

Consultation

Withheld under section 9(2)(h) [redacted]

Withheld under section 9(2)(h) [redacted]

Withheld under section 9(2)(h) [redacted]

Withheld under section 9(2)(h) [redacted]

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Procurement

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Te Tiriti o Waitangi

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Impact for Māori

Diabetes disproportionately affects Māori compared to non-Māori, in terms of diagnosis rates, age at diagnosis and development of complications. Matehuka diabetes has been identified by Māori as the second most important of the five hauora arotahi Māori health areas of focus for PHARMAC This proposal therefore represents an opportunity to support Māori to advance their aspirations for health. Furthermore, this represents an opportunity to address inequities in outcomes for Māori who are at high risk of cardiovascular and renal complications The recent publication by Vitz et al highlights this (Vitz M et al, NZMJ 2020;133(1523):76-86,).

We acknowledge the process undertaken for the initial development of this proposal did not uphold the articles of Te Tiriti o Watiangi, which would see stronger Māori input into its design and development. This is not unique to this transaction; to date our processes for funding proposals have not included the involvement of our Tiriti partners in proposal development Rather we partner with Māori in developing some of our overall strategic approach, and we engage during consultation. Feedback from Māori is overall supportive of funding these medicines However, there is concern from Māori, raised during consultation on this proposal, that the SA criteria may further disadvantage Māori for a variety of reasons. We have worked with Māori (through ongoing engagement with Urutā) to improve the SA criteria. While Urutā have made it clear that they do not support anything less than direct access for Māori, they

reservedly and reluctantly acknowledge, without prejudice, that the proposed criteria are a step forward

We plan to work alongside Māori representative groups to implement the funding of these new medicines and actively monitor Māori access and uptake to understand and develop ways to address equity and access gaps We are also separately undertaking broader policy work on this matter, which while outside of the scope of this transaction will be informed in part by our experiences with this transaction

Equity Implications

Diabetes has been identified as one of our areas of focus for medicines access equity.

PHARMAC staff consider that the proposal is a significant step towards enhancing health equity in Aotearoa New Zealand, that acknowledges the concerns raised by stakeholders during consultation.

We consider that targeted funding by SA is the only current fiscally viable option available to enable funded access to the two new medicines that have the potential to address substantial gaps in outcomes equity for type 2 diabetes amongst Māori and Pacific people. This view is supported by some of our consultation feedback.

The SA criteria have been developed to specifically target those people, including Māori and Pacific people, who have the greatest need and highest potential for benefit from these medicines The recent work by Vitz et al has tested the original proposed criteria against patient cohorts in Aotearoa New Zealand, and supports this assertion (Vitz M et al, NZMJ 2020;133(1523):76 86). The criteria have been further refined following careful consideration of consultation feedback, including with direct consideration to medicines access equity

We have developed methodology for measuring medicines access equity specific to type 2 diabetes If this funding proposal is approved, this methodology could be applied to the new medicines with a view to influencing equitable access drivers across the health sector. Furthermore, we are working to develop methodology for timely monitoring of uptake with an equity lens Should this proposal be approved, PHARMAC would look to publish this data in a way that would enable the sector to understand where access could be improved.

We consider that some of the concerns raised during consultation relate to the use of SA overall as a tool to target medicines to those at greatest need/potential to benefit (within available budget), with this proposal being one example Issues of the use of SA criteria to target medicines to specific groups is the subject of ongoing policy work

Financial Implications

The financial implications of this proposal are outlined in the Cost and Savings discussion under the Factors for Consideration section of this paper and in the summary budget impact analyses in the Executive Summary section of this paper.

Implementation Support and Communication

Section 49(b) of the Act requires PHARMAC to take measures to inform the public, groups and individuals of PHARMAC's decisions concerning the Pharmaceutical Schedule Accordingly, if the recommendations contained in this paper are adopted, we would implement the implementation plan included in Appendix Five The key focus areas of this plan are to:

- monitor and support the uptake of these medicines to ensure it is equitable, with a key focus on Māori and Pacific people;
- ensure clinicians and prescribers are aware of the funded options and are able to support their patients with initiating these treatments;
- ensure people who may benefit from these treatments are aware of them; and
- engage with the wider health sector about concerns related to equitable access (that are outside the roles and responsibilities of PHARMAC).

In particular, we are utilising our responsible use contract (Matui, under the brand He Ako Hiringa) to focus upcoming resource deliverables on equitable access and use of medicines in relation to diabetes. This work has begun with general information about medicines access equity and diabetes. Matui has developed a plan for work to support the uptake of these treatments, should this proposal be approved This includes several other workstreams, such as the development of the NZSSD Type 2 diabetes management guidelines, to ensure the work produced by Matui is not duplicative.

If approved, we would notify of this decision via our usual channels. We would also provide personalised notifications to the groups and individuals who responded to our consultation

Appendices

Appendix One: Resolutions

Appendix Two: Summary of consultation responses, consultation responses, and selected correspondence from after the close of consultation

Appendix Three: Compiled PTAC and SC advice received following consultation

Appendix Four: Clinical advisor conflicts of interest report

Appendix Five: Implementation plan