PHARMACEUTICAL SCHEDULE APPLICATION

To: **Diabetes Advisory Committee**

From: Therapeutic Group Manager

Date: June 2025

SGLT2i and GLP-1a Special Authority Criteria – Review

PURPOSE OF THIS PAPER

The purpose of this paper is to seek advice from the Committee to determine whether the current Special Authority criteria (SA2048) for access to SGLT2i (empagliflozin and empagliflozin with metformin) and GLP-1a (dulaglutide SA2338 and liraglutide SA2440), both classes listed from February 2021 and which contain specific ethnicity based aspects, remain appropriate.

The primary focus is to ensure that the criteria are consistent with the main policy in relation to Pharmac's operations, notably the 2024-2025 Letter of Expectations (the LOE) and the Cabinet Circular of 13 September 2024, titled Needs-based Service Provision (the Cabinet Circular), while still being compliant with section 6 and section 7 of the Pae Ora (Healthy Futures) Act 2022 (**the Act**). Also relevant is the Government Policy Statement on Health 2024-2027 (the GPS).

We seek advice on whether the ethnicity criteria the current Special Authority for these medicines could be amended. We would like to understand how we can ensure access for those people with the target health need through the Special Authority and other clinical criteria.

QUESTIONS TO COMMITTEE

Health need

1) What are the current barriers to Māori / Pacific people achieving access to a clinically appropriate treatment for Type 2 diabetes?
2) Since these treatments were funded, have there been any changes in clinical practice, specifically in the treatment of Māori/Pacific people?
3) Do you consider that the current Special Authority criteria contribute to addressing the health need of Māori and Pacific people and the New Zealand population?
    a. If so, how?
4) Do you consider that the current eligibility criteria disadvantage other populations who could benefit from access to SGLT2i / GLP-1a medicines ?
    a. If so, who are these groups and which criteria?

Special Authority criteria

5) As ethnicity is now a factor in the cardiovascular risk (CVR) assessment tools used universally in New Zealand, would the majority of Māori / Pacific People in need of SGLT2i/GLP-1a therapy now meet the 15% CVR threshold in the current criteria?
    a. If not, why not?
    b. How do our current SA criteria align or not align with this tool and any other tools used in clinical practice in NZ?
6) If possible, how would the criteria best be amended to ensure that those Māori or Pacific people who currently can access SGLTi / GLP-1a medicines via the ethnicity criteria would still be able to do so in the future?
    a. If this is not possible, how could the criteria be amended to limit the impact of any change and enable Māori and Pacific people to maintain a similar level of access?
    b. Do the proposed criteria preserve access to the currently funded patient group?
7) Are there any other aspects of the current SA criteria that you consider as requiring changes to better meet clinical need for the intended target population?
    a. If so, what?

Costs and Savings

8) How would the changes described above impact access to SGLT2i / GLP-1a medicines ?
    a. To what degree would usage change for Māori / Pacific people with T2DM and/or those at risk of cardio-renal complications ?
    b. To what degree would usage increase across the various indications for which the medicines are funded?

Other

9) Do you have any additional comments?

BACKGROUND

A SGLT2i (empagliflozin – brand Jardiance) and a GLP-1a (dulaglutide - brand Trulicity) were listed from February 2021 and September 2021, respectively for the treatment of type 2 diabetes with cardio-renal risk factors, with both Special Authority criteria including specific ethnicity criteria for Māori and Pacific Peoples. These ethnicity criteria were included following extensive consultation feedback (attached in Appendix One) and the following process as described below.

In September 2020 a consultation was issued seeking feedback on the proposed eligibility criteria for funding empagliflozin and dulaglutide, which had been selected as the preferred products following an RFP issued in January 2020. The proposed criteria detailed in the consultation had been informed by advice from the Diabetes Advisory Committee at a meeting held in March 2019. Consultation responses received were supportive of funding

the new diabetes medicines however, there was significant feedback relating to the issue of equity for Māori and Pacific populations.

Consultation feedback was received from around sixty different individuals, clinician and patient organisations. The feedback received covered a number of issues that, 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 funding decisions.

Subsequent to the close of the consultation, Pharmac staff met with a number of groups who had raised significant questions, including Te Rōpū Whakakaupapa Urutā (Urutā – which comprised leading Māori medical and health experts), Diabetes Foundation Aotearoa and the Pan-Pacific Nurses Association. Pharmac staff also offered to meet with the RACP and Te Ohu Rata o Aotearoa (Te ORA), but these two groups indicated that any engagement with Urutā would likely represent their views as well, noting that some members of Urutā were also members of Te Ora.

Equity concerns raised:

The most significant concerns raised by respondents related to access equity issues. Urutā's feedback was the most comprehensive and reflected sentiments expressed by other submitters. In summary:

Theme	**Detail**
The proposal failed to acknowledge persisting inequities in healthcare access, delivery and outcomes	Urutā discussed 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 considered this (SA in its current form) caused an additional barrier to accessing treatment for Māori.
The proposals did not recognise the increased risk of secondary complications in Māori living with type two diabetes	Urutā discussed 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 would increase ethnic inequity in access to medicines	Urutā discussed 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 discussed 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.

Following an extensive period of additional consultation following the feedback received, it was proposed that, in order to address the concerns regarding equity raised specifically by Urutā, that explicit criteria would be proposed that targeted those of Māori and Pacific ethnicity for access. This criteria change waived the requirement for confirmed cardiovascular risk or diabetic renal disease if the person was of either Māori or Pacific ethnicity.

In order to include ethnicity criteria in the Special Authority it was noted that the situation had to meet definitive requirements. This was based on independent legal opinion sought at the time of the consideration that it was permissible under both the NZ Public Health Act (enacting Pharmac at that time) and NZ's anti-discrimination legislation for Pharmac to use ethnicity as a criterion in circumstances where its aim is to address health disparities by targeting treatments to those most in need (as types of affirmative 'Special Measures' under The New Zealand Bill of Rights Act and The Human Rights Act). However, specific requirements had to be met in each case where an ethnicity criterion is adopted.

The key requirements that needed to be met to include any ethnicity criteria were:

- *The inclusion of ethnicity criteria 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*
- *The inclusion of ethnicity criteria considers whether there may be reasonable (and similarly effective) alternative solutions that do not involve making distinctions on the basis of ethnicity*
- *There is a real prospect that the inclusion of ethnicity in access criteria will address the disadvantage that is identified*
- *The inclusion of ethnicity criteria 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 who may need it are denied the benefit because they belong to a group considered not to be disadvantaged)*
- *The inclusion of ethnicity criteria 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 inclusion of ethnicity criteria means Pharmac regularly monitors and evaluates the effectiveness of using ethnicity as an access criterion*

The following table summarises key aspects of Pharmac's assessment at the time as to how each of these requirements would have been met. In summary:

Requirement	**Summary of PHARMAC staff assessment 2020/2021**
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, with disease burden 6-7 times that of non-Māori/non-Pacific people, and they 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.
There is a real prospect that the inclusion of ethnicity in access criteria	PHARMAC has received consultation feedback from recognised experts, that the inclusion of an ethnicity criteria has the genuine potential to address the disadvantage.

Requirement	Summary of PHARMAC staff assessment 2020/2021
will address the disadvantage that is identified	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. 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.
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. 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	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

Requirement	Summary of PHARMAC staff assessment 2020/2021
group, while others who may need it are denied the benefit because they belong to a group considered not to be disadvantaged)	Counties Manukau DHB). People 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.

Further detail is available in **Appendix Two**, including evidence sources. This information was considered by decision-makers in late 2020 and in 2021, alongside other factors and issues.

Supply Issues for GLP-1a agents

With the demand for dulaglutide far exceeding the initial expectations (initial estimate 5300 patients), the supplier (Eli Lilly) informed in late 2022 that they were unable to supply the market demand due to the rapid uptake of the medicine, in March 2023 liraglutide (Victoza) was listed to enable continued access for new patients to a GLP-1a medicine. Further difficulties with supply from both Eli Lilly and Novo Nordisk led to the decision to restrict both medicines to existing patients only from 1 May 2024.

Access for new patients to liraglutide was reinstated from March 2025, while dulaglutide will be available for new patients from 1 July. When reinstating access, it was agreed that the criteria for empagliflozin and liraglutide/dulaglutide would be reviewed.

Current funding criteria for SGLT2i and GLP-1a medicines for T2DM

The following are the currently active Special Authority Criteria for SGLT2i and GLP-1a medicines respectively:

> *Empagliflozin / empagliflozin with metformin is currently funded subject to the following Special Authority criteria (Type 2 Diabetes Indication):*
>
> **Special Authority for Subsidy**
> Initiation – **Type 2 Diabetes**
> Any of the following:
> 1. For continuation use; or
> 2. Patient has previously had an initial approval for a GLP-1 agonist; or
> 3. All of the following:
> 3.1. Patient has type 2 diabetes; and
> 3.2. Any of the following:
> 3.2.1. Patient is Māori or any Pacific ethnicity*; or
> 3.2.2. Patient has pre-existing cardiovascular disease or risk equivalent (see note a)*; or

3.2.3. Patient has an absolute 5-year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator*; or
3.2.4. Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult*; or
3.2.5. Patient has diabetic kidney disease (see note b)*; and
3.3. 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.

Notes: * Criteria intended to describe patients at high risk of cardiovascular or renal complications of diabetes.
a) Pre-existing cardiovascular disease or risk equivalent 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.
b) Diabetic kidney disease 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.
c) Funded [empagliflozin / empagliflozin with metformin hydrochloride] treatment is not to be given in combination with a funded GLP-1 unless receiving (empagliflozin / empagliflozin with metformin hydrochloride] for the treatment of heart failure.

Liraglutide is currently funded subject to the following Special Authority criteria:

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:
All of the following:
1. Patient has type 2 diabetes; and
2. Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the regular use of all of the following funded blood glucose lowering agents for a period of least 6 months, where clinically appropriate: empagliflozin, metformin, and vildagliptin; and
3. Any of the following:
   3.1. Patient is Māori or any Pacific ethnicity*; or
   3.2. Patient has pre-existing cardiovascular disease or risk equivalent (see note a)*; or
   3.3. Patient has an absolute 5-year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator*; or
   3.4. Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult*; or
   3.5. Patient has diabetic kidney disease (see note b)*.

Notes: * Criteria intended to describe patients at high risk of cardiovascular or renal complications of diabetes.
a) Pre-existing cardiovascular disease or risk equivalent 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.
b) Diabetic kidney disease 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 identified.
c) Funded GLP-1a treatment is not to be given in combination with (empagliflozin / empagliflozin with metformin hydrochloride) unless receiving (empagliflozin or empagliflozin in combination with metformin hydrochloride) for the treatment of heart failure.

HEALTH NEED

Type two diabetes mellitus (T2DM) impacts a significant number of NZ adults and the incidence is expected to increase with time. The increasing prevalence already impacts NZ's health care system but the burden of disease on both patients and the sector is expected to increase exponentially in future (see Teng et al. NZMJ. 2025;138(1608)).

In the 2023/24 FY there were 88,000 people receiving empagliflozin / empagliflozin with metformin and 31,000 people receiving one of the 2 funded GLP-1a medicines.

Māori and Pacific adults are particularly impacted by type 2 diabetes – not only are these population groups more likely to have type 2 diabetes compared with other ethnic groups, 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.

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 and Māori and Pacific children are disproportionately impacted by T2DM, particularly when compared with NZ European children.

Barriers to T2DM primary care

A number of barriers to optimal primary health care for T2DM in NZ have been canvassed in recent qualitative analysis (Norman et al. General practitioner and nurse experiences of type 2 diabetes management and prescribing in primary care: a qualitative review following the introduction of funded SGLT2i/GLP1RA medications in Aotearoa New Zealand. Prim Health Care Res Dev. 2024;25:e34).

Cardiovascular risk assessment

The Cardiovascular Disease Risk Assessment (CVDRA) Tool, which is based on updated multivariate risk equations from the PREDICT cohort[1], assesses individual cardiovascular risk that incorporates relative weighting for people in ethnic groups with higher risk. The CVDRA is used universally in New Zealand to assess cardiovascular risk and is readily available via https://www.heartfoundation.org.nz/professionals/health-professionals/cvd-consensus-summary, and the VAREANZ CVD risk calculator specific to T2DM population is available via the NZSSD website at https://uoaview2.shinyapps.io/T2DNoPriorCVD/.

Access to cardiovascular risk assessment and then effective access to actual treatment (including with SGLT2i and GLP-1a diabetes medicines) is part of addressing the high inequitable diabetes and cardiovascular need in Māori and Pacific peoples.
A recent systematic review (Wheeler et al. Lancet Reg Health West Pac. 2025;56:101511) has assessed such access to CVDRA assessment and primary care management for Māori and Pacific peoples in NZ, as well as factors contributing to reduced access. Relevant to CVD risk assessment, the authors reported:

[1] Pylypchuk R, Wells S, Kerr A, et al. Cardiovascular disease risk prediction equations in 400 000 primary care patients in New Zealand: a derivation and validation study. Lancet. 2018;391(10133):1897-1907. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)30664-0/fulltext

HISO 10071:2019 Cardiovascular Disease Risk Assessment Data Standard. https://www.tewhatuora.govt.nz/publications/hiso-100712019-cardiovascular-disease-risk-assessment-data-standard,

https://www.tewhatuora.govt.nz/assets/Our-health-system/Digital-health/Health-information-standards/HISO-10071-2019-CVD-Risk-Assessment-Data-Standard.pdf

- Extensive and inequitable gaps in CVDRA and management for Māori and Pacific peoples (compared with other ethnicities) were identified
- Levels of CVDRA were inadequate in Māori and Pacific peoples when measured against the 90% national target.
- Factors contributing to CVDRA and management, and opportunities to reduce gaps, were providing adequate CVD health literacy, involvement of whanāu, patient-provider relationships, access to care, and enhancing cultural safety.

This review is provided as Attachment 1.

UPTAKE OF SGLT2I/GLP-1A SINCE THE 2020/2021 ACCESS CHANGES

Analysis of take-up of funded SGTL2i and GLP1 agonists since the 2021 changes to SA criteria have indicated higher differential increases in uptake in Māori and Pacific peoples compared with other ethnicities:

Access check up

In August 2023 Pharmac carried out an Access check-up project (Attachment 2) to help gauge how well current access criteria were working in identifying target populations for empagliflozin and dulaglutide. The key questions for this project were:

a) What was the effect of the ethnicity criteria?

b) Were there people with brittle (hard to control) Type 2 diabetes at high risk of cardiovascular criteria who could not meet the Special Authority access criteria?

A data science organisation was engaged to access primary care data in relation to people with T2DM and a high risk of cardiovascular and renal complications, this was undertaken in collaboration with eleven PHOs, each with a high proportion of Māori and Pacific peoples in their populations.

Overall, the project looked at 1.9 million people (37% of the NZ population) of which 91,000 people were coded as having T2DM. Nearly half (46%) of people with T2DM met the current SA access criteria.

It was found that for the sample population that Māori and Pacific peoples had a high level of clinical indicator recording (cardiovascular and renal risk), which was equivalent to or higher than other ethnic groups, eg. cardiovascular risk assessment for Māori was 91% versus 83% for non-Māori. The analysis suggested that any prior inequities in access to cardiovascular and renal risk assessment testing for Māori and Pacific peoples with T2DM appeared to be no longer apparent, leading to high clinical eligibility for these priority populations via the clinical criteria alone. Also noted was that the major CVRA tools now include weightings for ethnicity where risk is higher.

The analysis also reported that Māori and Pacific people were more likely to be prescribed SGLT2i/GLP-1a medicines compared to other ethnicities. It was estimated that 89% of Māori and Pacific peoples would meet the access criteria through the clinical criteria only.

The analysis noted that the intended target population for funded access to these medicines was:

"People with T2DM at high risk of cardiovascular and renal complications where glycaemic control has not been achieved using first-line agents:

It was also noted in the analysis that people not captured by the current special authority criteria included non-Māori, non-Pacific peoples at high risk of CV/renal complications of T2DM who either do not have clinical indicator recordings or have high risk markers not included as part of the SA access criteria.

It was reported that there was no difference in eligibility or prescription access for rural versus urban location. It was determined that there were non-Māori/non-Pacific people who were part of the intended funded population who were unable to meet the clinical access criteria. Those who were aged less than 40 years and greater than 70 years of age and of female gender were identified as specific demographics who had restricted access.

Key takeaways from the report

The report noted that there were 2 main options that could be employed to ensure a greater level of access to SGLT2i/GLP-1a medicines in the absence of specific ethnicity criteria:

1. Add a greater suite of clinical markers to the SA criteria (eg. BMI, noting that for people with T2DM who did not meet the current SA clinical indicators almost 50% had a BMI > 30), albeit noting possible difficulties in applying universal BMI measures across ethnicities
2. Include a prescriber determined high risk of CV/renal complications.

Option (b) would give prescribers clinical discretion to mitigate for clinical diversity of presentation. Guidance could be given to prescribers as to what specific circumstances should be considered, this would not be considered to be a widening of access but rather an approach to ensure a more inclusive way of capturing the intended population.

Real world initiation of newly funded empagliflozin and dulaglutide under special authority for patients with type 2 diabetes in New Zealand

This recently published cohort study (Chepulis et al. BMC Health Serv Res. 2025;25(1):433) examined patient and practice-level variables associated with the initiation of SGLT2i/GLP-1a prescribing in people with T2DM in NZ. Findings included:

- Nearly half of eligible individuals with T2DM were prescribed SGLT2i/GLP-1a under SA criteria in the 18-months following those agents' February 2021 funded availability.
- 17·8% of all patients with T2D were prescribed these medications, with nearly a third of all Māori and Pacific patients with T2DM being prescribed.
- Of 57,743 patients with T2D, 22,331 were eligible for funded SGLT2i/GLP-1a access and 10,272 of those (46.0%) were prescribed.
- Initiation of therapy was highest in Māori (50.8%) and Pacific (48.8%) patients (vs. 36·2–40·7% of other ethnic groups; $P < 0.001$), but was comparable in those with and without CVRD (47·1% vs. 48·9%; $P = 0.2$).
- Prescribing was highest in practices with higher doctor/patient numbers, low-cost fees, Māori health providers and clinics without after-hours access.

This study is provided as Attachment 3.

REVIEW OF SGLT2I/GLP-1A SPECIAL AUTHORITY CRITERIA

Potential amendments to the criteria

In order to implement the Board's decision on giving effect to the 2024-2025 Letter of Expectations (the LOE) and the Cabinet Circular of 13 September 2024 titled 'Needs-based Service Provision' (the Cabinet Circular), we need to ensure that the criteria for access to SGLT2i and GLP-1a are evidence based and use clinical markers of health.

To support consideration of this, please see the following potential Special Authority criteria that seek to consider:

- The necessity for an explicit ethnicity criterion
- The need to be explicit in defining cardiovascular disease risk
- The need to define the renal risk
- The option to allow prescriber discretion in determining access.

We seek advice from the Committee as it relates to each component of the criteria (highlighted), to ensure that we understand the most appropriate changes required. We would like to understand the impact of these changes in clinical practice, specifically how they would increase, or decrease the use of empagliflozin / dulaglutide / liraglutide.

Possible empagliflozin / empagliflozin with metformin Special Authority criteria (T2DM indication)

Initial application — (Type 2 Diabetes) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:
Either:
1. Patient has previously had an initial approval for a GLP-1 agonist; or
2. All of the following:
   2.1. Patient has type 2 diabetes; and
   2.2. Any of the following:
      ~~2.2.1. Patient is Māori or any Pacific ethnicity*; or~~
      2.2.2. Patient has pre-existing cardiovascular disease or risk equivalent (see note a)*; or
      2.2.3. Patient has an absolute 5-year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator*; or
      2.2.4. Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult*; or
      2.2.5. Patient has diabetic kidney disease (see note b)* or
      2.2.6. In the opinion of the treating relevant practitioner the patient is at high risk of cardiovascular or renal complications of type 2 diabetes; and
   2.3. 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.

Notes: * Criteria intended to describe patients at high risk of cardiovascular or renal complications of diabetes.
a) Pre-existing cardiovascular disease or risk equivalent 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.
b) Diabetic kidney disease 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.
c) Funded [empagliflozin / empagliflozin with metformin hydrochloride] treatment is not to be

given in combination with a funded GLP-1 unless receiving (empagliflozin / empagliflozin with metformin hydrochloride] for the treatment of heart failure.

Possible dulaglutide/liraglutide Special Authority criteria

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

1. Patient has type 2 diabetes; and
2. Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the regular use of all of the following funded blood glucose lowering agents for a period of least 6 months, where clinically appropriate: empagliflozin, metformin, and vildagliptin; and
3. Any of the following:
   - ~~3.1. Patient is Māori or any Pacific ethnicity*; or~~
   - 3.2. Patient has pre-existing cardiovascular disease or risk equivalent (see note a)*; or
   - 3.3. Patient has an absolute 5-year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator*; or
   - 3.4. Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult*; or
   - 3.5. Patient has diabetic kidney disease (see note b)*or
   - 3.6. In the opinion of the treating relevant practitioner the patient is at high risk of cardiovascular or renal complications of type 2 diabetes

Notes: * Criteria intended to describe patients at high risk of cardiovascular or renal complications of diabetes.
a) Pre-existing cardiovascular disease or risk equivalent 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.
b) Diabetic kidney disease 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 identified.
c) Funded GLP-1a treatment is not to be given in combination with (empagliflozin / empagliflozin with metformin hydrochloride) unless receiving (empagliflozin or empagliflozin in combination with metformin hydrochloride) for the treatment of heart failure.

CURRENT USAGE / ECONOMICS

Figure 1 shows the relative proportion of patients by ethnicity dispensed empagliflozin or empagliflozin with metformin. Notable is that the high-risk populations account for 53% of the total number of patients dispensed these medicines (88,000)

***Figure 1**: Patient dispensing by ethnicity 2023/24 – SGLT2i*

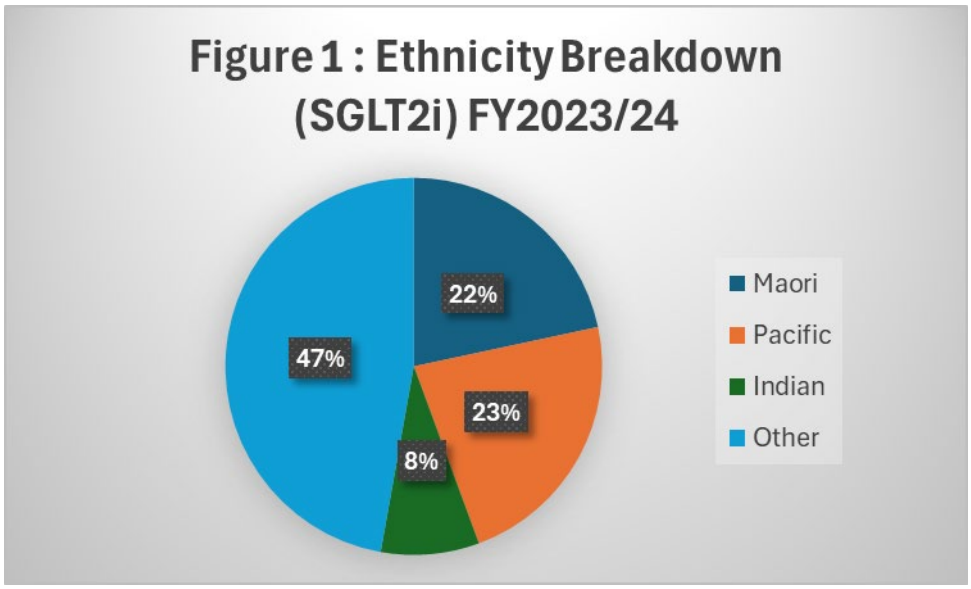


Figure 2 shows the relative proportion of patients by ethnicity dispensed dulaglutide/liraglutide. Notable is the higher proportion of Māori on a GLP-1a rather than an SGLT2i medicine, with Pacific peoples proportionately lower than for SGLT2i (31,000)

***Figure 2**: Patient dispensing by ethnicity 2023/24 – GLP-1a*

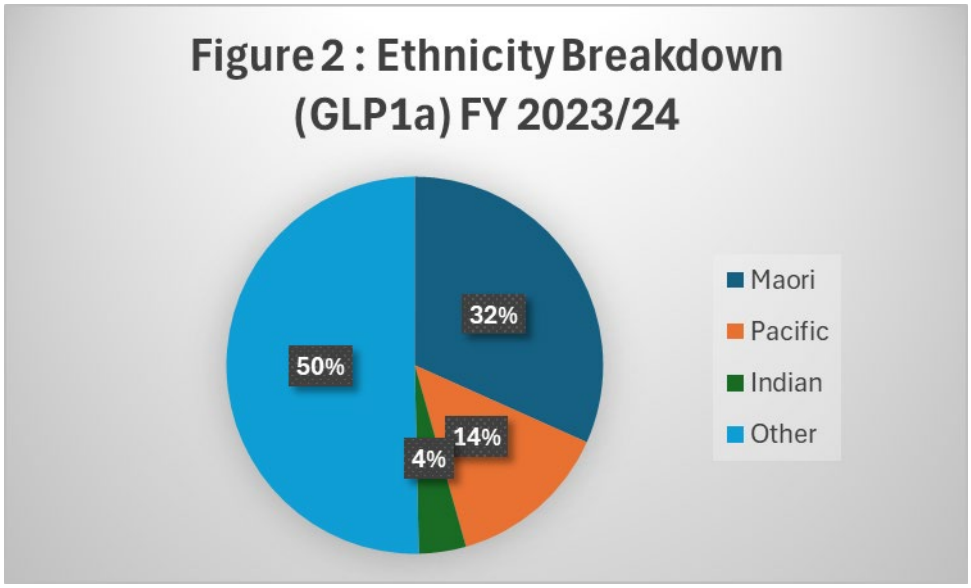


Table 3 shows the relative breakdown of categories for which Special Authorities have been approved for the GLP-1a medicines, with approximately 38% checking the Māori/Pacific option.

***Table 3**: Special Authority by Indication GLP-1a*

Special Authority by Indication : (Dulaglutide / liraglutide) since listing	%
Patient is Maori or any Pacific ethnicity	37.7%
Patient has pre-existing cardiovascular disease or risk equivalent	15.8%
Patient has an absolute 5 year CV disease risk of 15% or greater according to a validated CVR assessment calculator	25.8%
Patient has a high lifetime cardiovascular risk due to being diagnosed with T2DM during childhood or as a young adult	10.7%
Patient has diabetic kidney disease	10.0%

Table 4 shows the relative change in ethnicity pre and post the funding of SGLT2i/GLP-1a medicines, notable is that there has been a general growth in the number of people accessing medicines with similar growth in use across the ethnicities.

***Table 4:** Growth in use of T2DM medicines pre and post SGLT2i/GLP-1a funding*

Ethnicity Breakdown : T2 Diabetes medicines* pre and post SGLT2i / GLP1a funding					
Ethnicity	FY2019/2020	%	FY2023/2024	%	Growth
Maori	30,993	17%	48,245	18%	56%
Pacific	28,910	15%	43,048	16%	49%
Indian	15,836	8%	24,330	9%	54%
Other	110,857	59%	159,370	58%	44%
Total	186,596		274,993		47%

* Excludes Insulins

Appendices:

Appendix One: Summary of SGLT2i/GLP-1a consultation feedback in 2020/2021

Appendix Two: Pharmac staff consideration in 2020/2021 of the SGLT2i / GLP-1a funding proposals (which included ethnicity access criteria under 'Special Measures')

Attachments:

1. Wheeler A, Rahiri JL, Ellison-Lupena R, et al. Assessing the gaps in cardiovascular disease risk assessment and management in primary care for Māori and Pacific peoples in Aotearoa New Zealand- a systematic review. Lancet Reg Health West Pac. 2025;56:101511.

2. Empagliflozin/dulaglutide access check-up report, December 2023.

3. Chepulis L, Rodrigues M, Gan H, Keenan R, Kenealy T, Murphy R, et al. Real world initiation of newly funded empagliflozin and dulaglutide under special authority for patients with type 2 diabetes in New Zealand. BMC Health Serv Res. 2025;25(1):433.

APPENDICES

Appendix 1: Summary of relevant SGLT2i / GLP-1a consultation feedback (from notification) received in 2020/2021

Theme	Pharmac Response at the time
General topics	
A number of responders thought the 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 Special Authority criteria with the intentional view to further enhance the health equity focus of this proposal.
Some responders considered that Māori and Pacific people living with type 2 diabetes should have a direct pathway to access these medicines eg. via an equity criterion	We acknowledge that Māori and Pacific people are disproportionately impacted by type 2 diabetes. Following careful consideration of consultation feedback, we have amended the proposed Special Authority 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.
Special Authority criteria changes	
A number of responders requested that the criterion related to maximum tolerated dose of anti-diabetic treatments be clarified to only require metformin as a prior treatment	The Special Authority criteria have been amended to clarify that at least one prior anti-diabetes medicine (including, for example, metformin, vildagliptin or insulin) should have been used prior to treatment with empagliflozin or dulaglutide. We have also reduced the time requirement for assessing whether the prior treatment has worked, from 6 months to 3 months.
A number of responders considered the existence of Special Authority criteria would reduce the ability of Māori and other high-risk populations to access these treatments, and called for the removal of these criteria	s 9(2)(b)(ii) Furthermore, some people we engaged with held the view that pro-equity access criteria would be an active approach to addressing inequities, rather than a passive approach. We are aware of inequities in access to medicines that exist even when they are listed without any access criteria. Instead, we worked extensively with our clinical advisors and external clinician groups to develop Special Authority criteria that we consider to be pro-equity. The Special

Theme	Pharmac Response at the time
	Authority criteria specifically name Māori and Pacific ethnicities. We are aware that people of South Asian ethnicities may be at a higher risk of diabetes and its complications compared to other groups. However, data suggests that access to medicines for South Asian groups is, in general, equitable. [2] The Special Authority includes other criteria to identify those with high-risk disease that would be met by other groups, including people of South Asian ethnicities. We plan to work to support the sector with implementation activities with the express purpose of supporting equitable access to these medicines.
Some responders considered the proposed Special Authority criteria would not permit access by children and young adults with type 2 diabetes – a group 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 responders considered that there is a need for dual funding of SGLT-2 inhibitors together with GLP-1 agonists, including to reduce inequities in access	Concomitant use of a SGLT-2 inhibitor and GLP-1 agonist was outside of the scope of the RFP. 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. We would welcome a funding application for the concomitant use of these medicines.
Two respondents noted that the SA criteria rely on screening and testing (e.g., HbA1c, ACR, CV risk assessment) which they consider to be inequitably delivered and would increase and entrench inequity for Māori and Pacific people	Pharmac acknowledges that significant health inequities exist in Aotearoa New Zealand, that 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 proposed Special Authority criteria 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 Special Authority criteria to clarify that Māori and Pacific people meeting certain other criteria would have access to these medicines given the

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

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

Theme	Pharmac Response at the time
	heightened risk of cardiovascular and renal outcomes in these ethnic groups, and documented inequities in access to health care. We note that the criteria would still require that all people accessing these medicines have an HbA1c test, and to have tried at least one other medication for T2DM for at least 3 months.
Health equity – Pharmac processes	
A number of respondents considered that equity members should be added to PHARMAC's clinical advisory groups, and that PHARMAC should review its process for equity in funding decisions	We are working to enhance Pharmac's equity capabilities, including our processes related to funding decisions and when seeking clinical advice. 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 respondents 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 plan to report on this monitoring as part of our medicines access equity work, and specifically to support the ongoing implementation of these new medicines. We intend to work with the sector, including Māori health experts, to design our approach to this work and analysis of the results. This work is likely to be complex and may not be available in its final form at the first date of funding.
Implementation	
A number of respondents 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 has committed to strong working relationships with Māori as part of its commitment to upholding Te Tiriti or Waitangi as set out in Te Rautaki o Te Whaioranga – Māori Responsiveness strategy. 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.

Theme	Pharmac Response at the time
A number of respondents suggested that proactive identification and recall of eligible patients using clinical practice tools and systems will enhance access	We intend to encourage healthcare professionals to proactively identify their patients who would benefit most from treatment, as part of our implementation support activities. We are aware of the development of a tool to support PHOs to identify their patients who would benefit from treatment with an SGLT-2 inhibitor. This is being developed by the supplier Pharmac staff plan to actively monitor the uptake of these treatments and share outcomes by ethnicity and DHB region.
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 will work with the suppliers of these treatments to help ensure that meaningful patient information is co-created with the people who would be eligible for funded access to these treatments.
Sector costs	
One respondent 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.
Request for funding of other pharmaceuticals	
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.
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, that these are unacceptable. 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.

Appendix Two: Pharmac considerations in 2020 and 2021 of SGLTi/GLP-1a funding proposals that included ethnicity access criteria under 'Special Measures'

Specific requirements that must be met before adopting an ethnicity criterion are summarised as follows; that [the funder/agency] can include ethnicity as an access criterion where:

1. *The inclusion of ethnicity criteria 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*
2. *The inclusion of ethnicity criteria considers whether there may be reasonable (and similarly effective) alternative solutions that do not involve making distinctions on the basis of ethnicity*
3. *There is a real prospect that the inclusion of ethnicity in access criteria will address the disadvantage that is identified*
4. *The inclusion of ethnicity criteria 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 who may need it are denied the benefit because they belong to a group considered not to be disadvantaged)*
5. *The inclusion of ethnicity criteria 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*
6. *The inclusion of ethnicity criteria means Pharmac regularly monitors and evaluates the effectiveness of using ethnicity as an access criterion*

The proposed ethnicity-based access criteria for specific SGLT-2 inhibitors and GLP-1 agonists for T2DM are assessed against the above six elements as follows:

1) *Whether 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,[3] with a disease burden at least 6-7 times that of non-Māori/non-Pacific,[4] and have the capacity to benefit from these treatments. In addition, there

[3] 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.

[4] 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.)

is clear evidence that both population groups have been discriminated by the health system, which has been well documented.[5],[6],[7],[8]

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 times 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).

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 (45-6	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*

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

[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/

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.

[6] 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

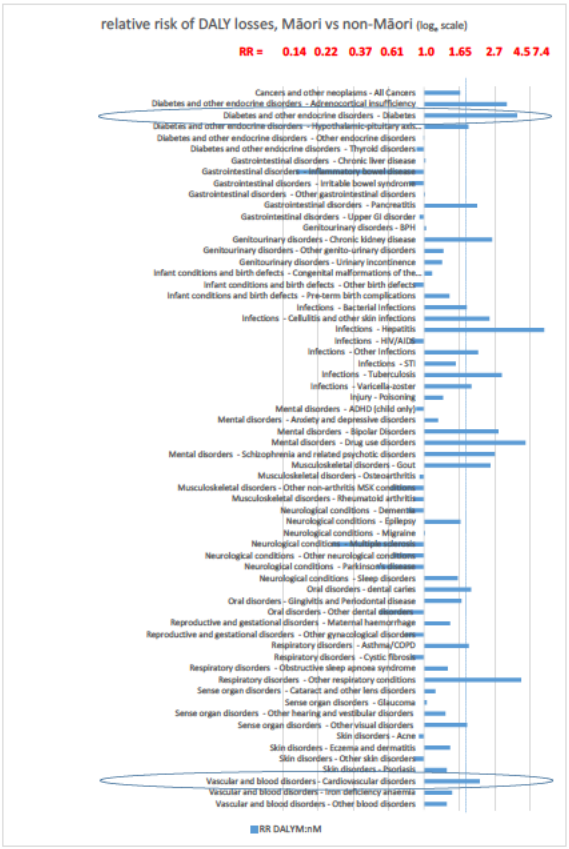
https://www.moh.govt.nz/notebook/nbbooks.nsf/0/A31842D91480064FCC256A55007A980A/$file/PrioritiesForMaoriandPacificHealth.pdf

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

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

[8] 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.

disease burden categories (exceeding arteriosclerotic cardiovascular disease and combined cancers; although these have numerically greater excess DALY losses in Māori/Pacific people):[9]



2) Whether there is a real prospect that including 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 criterion 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.[10],[11],[12] 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.

[9] PHARMAC staff analysis , 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/

[10] 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.

[11] 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/

[12] 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/

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) *Whether including ethnicity as an access criterion considers 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.[13]

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 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) *Whether including ethnicity as an access 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[14] (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

[13] 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).

[14] 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.

health services, as well-evidenced with the known ethnic inequities in needs (disease burden)-adjusted metformin access. [15],[16],[17]

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 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[18],[19], and in the context of the much greater impacts of socioeconomic deprivation, colonisation, racism etc.)

5) *Whether including ethnicity as an access criterion 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 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.

[15] 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.

[16] 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/

[17] 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/

[18] 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

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

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 Europeans and access rates much higher than Māori and Pacific peoples.[20] 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[21] (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.

[20] 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.

[21] 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.