PHARMAC
TE PĀTAKA WHAIORANGA

MEMORANDUM FOR PHARMAC BOARD MEETING

To:	Pharmac Directors
From:	Acting Director, Pharmaceuticals
Meeting Date:	30 September 2025
Item:	4.5

Options regarding removal of ethnicity criteria for diabetes medicines

Recommendations

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

- **agree** to proceed to consultation on the proposed approach (Option 3) to remove ethnicity criteria from the current special authority criteria for diabetes medicines and assess widening access through a reduction of the five-year cardiovascular risk threshold for everyone irrespective of ethnicity, as part of Pharmac's standard funding processes
- **note** the range of options for change considered
- s 9(2)(b)(ii), s 9(2)(f)(iv)
- **note** the significant cost of widening access to diabetes medicines, if progressed, and current budget availability
- **note** the proposed approach (Option 3) would not impact those individuals who currently have access through the existing criteria and would only affect access for new individuals.

1. Purpose

This paper seeks the Board's approval in principle to consult on removing ethnicity criteria from diabetes medicines. Widening access through a reduction in the five-year cardiovascular risk threshold would then be considered as part of Pharmac's standard funding processes and this would be communicated as part of the consultation.

The options presented in this paper are in response to the Board's request that the criteria for access to specific medicines for the treatment of type 2 diabetes and cardiovascular disease, better reflect the strategic direction (see below).

To support the Board's consideration, four options for the diabetes medicines are outlined, along with the estimated budgetary impact, cost effectiveness and risks/mitigations associated with each option. s 9(2)(b)(ii), s 9(2)(f)(iv)

2. Strategic Direction

The recommended proposal aligns with our purpose to deliver the best health outcomes from New Zealand's investment in medicines and medical devices, by making choices and managing expenditure and supply. The proposal aims to better identify individuals with the highest health need, through targeted clinical criteria. This aligns with the Cabinet Circular CO (24) 5 of 13 September 2024, titled 'Needs-based Service Provision' (the Cabinet Circular), the Letter of Expectations and Pharmac's position on section 6 and 7 of Pae Ora (Healthy Futures) Act 2022 (the Act).

3. Executive Summary

3.1. Currently, access to two classes of diabetes medicines (SGLTi and GLP1a) includes an ethnicity criterion targeting Māori and Pacific patients. This provides an alternative access pathway, without the need to meet explicit clinical criteria that define high cardio-renal risk.

3.2. s 9(2)(b)(ii) [redacted]

3.3. Clinical advice was sought from the Diabetes and Cardiovascular Advisory Committees in June 2025, regarding the ethnicity criteria and options to address levels of access if the specific ethnicity criteria were removed.

3.4. Pharmac staff propose four options to address removal of the current ethnicity criteria for diabetes medicines:

3.5. Summary of Options

Option 1: remove ethnicity criteria with no other changes proposed.

Option 2: remove ethnicity criteria and widen clinical criteria to a cardiovascular risk of greater than or equal to 10% (currently 15%) – this option has an estimated impact on the medicines budget of s 9(2)(b)(ii) [redacted].

Option 3 with two phases:

- Phase 1: remove ethnicity criteria – s 9(2)(b)(ii) [redacted]
- Phase 2: undertake a full health economic assessment of widened clinical criteria to a cardiovascular risk of greater than, or equal to 10% (versus 15%). A proposal to widen access would be formally ranked as an investment option and s 9(2)(b)(ii) [redacted]

Option 4: undertake a full health economic assessment of widened clinical criteria to a cardiovascular risk of greater than or equal to 10% (versus 15%), as s 9(2)(b)(ii) [redacted]

3.6. Pharmac staff note that removal of ethnicity criteria would likely result in considerable feedback, which could be mitigated to some extent through proactive engagement of identified key stakeholders, prior to consultation release.

4. Summary of Options - Advantages and Disadvantages

	Option 1	Option 2	Option 3	Option 4
Description	Remove ethnicity criteria for new patients starting treatment	Remove ethnicity criteria through widening access via cardiovascular risk disease (CVD) risk score	Remove ethnicity criteria then consider application for widened access via prioritisation process	Consider application for widened access and remove ethnicity criteria when proposal can be funded
Advantages	Rapid compliance with cabinet circular s 9(2)(b)	Rapid compliance with cabinet circular Aligns with expert advice and evidence	Rapid compliance with cabinet circular Allows for thorough assessment and ranking of widening access s 9(2)(b)(ii)	Retains access for Māori and Pacific peoples via the ethnicity criteria until widened access is funded Allows for thorough assessment and ranking Aligns with expert advice and evidence
Disadvantages	Reduces access to Māori and Pacific patients with no enhanced clinical criteria access Reputational risk with clinicians and consumers	s 9(2)(b)(ii)	Reduces access to those with higher health need until widened access funded Reputational risk if assessment ranks low and/or funding is delayed	Removal of ethnicity criteria occurs later

5. Background and Context

The current Special Authority criteria for SGLT2i (empagliflozin) and GLP-1a (liraglutide, dulaglutide) medicines for type 2 diabetes, include 'Patient is Māori or any Pacific ethnicity' as a key descriptor, defining access to treatment.

In December 2020, the Pharmac Board considered a proposal to fund SGLT2i (empagliflozin and empagliflozin with metformin) and the GLP-1a dulaglutide. These were funded from February 2021 and September 2021 respectively, with specific ethnicity-based criteria included. At this time, the legal-based requirements for inclusion of ethnicity criteria were considered.

Specifically, it was deemed possible for Pharmac to use ethnicity to address health disparities by targeting treatments to those people most in need, as 'Special Measures' under The New Zealand Bill of Rights Act and The Human Rights Act. Specific requirements had to be met in each case where an ethnicity criterion was to be adopted. These requirements were addressed in the December 2020 Board paper.

6. 2025 Review of Ethnicity Criteria

Pharmac staff have reviewed the ethnicity criteria to ensure that they meet the Government's public services expectations in the Cabinet Circular. This requires that any targeted investments must have empirical evidence about why such interventions are necessary. Pharmac interprets this to mean it is tasked with ensuring the criteria for access to SGLT2i and GLP-1a medicines are evidence-based and use clinical markers of health.

6.1. Summary of clinical advice received

Pharmac staff convened a meeting of the Diabetes Specialist Advisory Committee in June 2025. A copy of the meeting record is provided in Appendix 1 (approved by the Committee Chair, to be published post Board discussion). The expert advice sought was specifically in relation to whether the use of ethnicity criteria was still clinically relevant in facilitating access to the intended target population for SGLT2i and GLP1a medicines, taking into consideration the direction defined in the Cabinet Circular.

A summary of the advice received from the Diabetes Advisory Committee is outlined below:

- **Health benefit and access widening**
    - The Committee agreed that broader access to SGLT2i and GLP-1a medicines for people with type 2 diabetes - beyond current funding criteria, would likely yield significant health benefits.
- **Special Measures justification**
    - Māori and Pacific peoples face entrenched systemic barriers to healthcare access and ethnicity remains a necessary component of the Special Authority criteria to address these inequities, as no alternative criteria effectively capture the unique risks and needs of these populations.
    - Māori and Pacific peoples have a disproportionately high burden of type 2 diabetes cardio-renal disease (6–7 times higher than other groups) and lower dispensing rates.
    - The health system was not adequately meeting their needs, and ethnicity-based criteria were necessary to address entrenched inequities. Māori and Pacific peoples face entrenched systemic barriers to healthcare access.
    - South Asian groups, while at higher risk, do not face the same systemic barriers and are adequately captured by other clinical criteria.
- **Pharmac analysis and prescribing trends**
    - The Committee reviewed a December 2023 Pharmac check-up analysis (Appendix 2) of the effectiveness of the access criteria for empagliflozin and dulaglutide and noted that the analysis indicated that ~89% of Māori and Pacific

peoples with type 2 diabetes meet current clinical criteria independently of the ethnicity access option.

- The Committee also noted that the analysis showed cardiovascular risk assessments are more frequently conducted for Māori (91%) than non-Māori (83%), indicating an improvement in access since the original consideration.

- The Committee reviewed an independent study that found that nearly half of eligible patients were prescribed SGLT2i/GLP-1a within 18 months of funding availability, with Māori and Pacific patients having the highest initiation rates (50.8% and 48.8%, respectively).

- **Clinical criteria and risk assessment tools**

  - Multiple cardiovascular risk tools are used inconsistently, especially in how they factor in ethnicity.

  - The current special authority form may inadvertently enable prescribers to avoid undertaking a thorough clinical assessment including cardiovascular risk assessment/scoring for Māori and Pacific peoples.

  - The current 15% 5-year cardiovascular risk threshold may be too high; New Zealand Society for the Study Diabetes (NZSSD) guidelines are under review and may lower this threshold.

  - Introducing discretionary criteria based on prescriber judgment of cardio-renal risk could improve inclusivity and better capture the intended target population. However, this approach may risk under-assessment of clinical risk and would have significant budgetary implications.

  - The intent of a criterion is not to explicitly guide clinical practice nor serve as an educational tool but to ensure that funded access was targeted to the defined population for which funded medicine access was intended.

Pharmac staff note the advice received from the Committee continued to support the use of ethnicity criteria where there were no other reasonable means to allow access to individuals with the highest health need.

6.2. Options to consider

Taking this advice into consideration, Pharmac staff propose four possible options for the Pharmac Board to consider for removal of the ethnicity criterion from the Special Authority criteria for SGLT2i and GLP1a. We consider that this reasonably represents the scope for change if the ethnicity criterion were to be removed.

Option 1: Remove ethnicity criterion with no other changes

Option 2: Widen access by reducing the CVD risk threshold and remove reference to ethnicity criteria at the same time

Option 3: Remove ethnicity criterion and assess widening access, of reducing the five-year cardiovascular risk threshold, as part of Pharmac's standard funding processes.

Option 4: Assess widening access by reducing the five-year cardiovascular risk threshold, delay removal of ethnicity criteria s 9(2)(b)(ii)

All options for removal have risks. More detail on these options, including risks and mitigations, is provided in Appendix three.

7. Rationale for recommended option (Option 3: Remove ethnicity criterion, with a proposal to widen access by reducing the five-year cardiovascular risk threshold as part of Pharmac's standard funding process)

Pharmac staff consider that Option 3 incorporates a balance of proposed widened access through the clinical criteria and the removal of the ethnicity component. The implementation would be split into two phases. The proposed widened access (Phase 2) would follow the usual medicines funding process and would be subject to relative ranking on the Options for Investment List (OFI) and s 9(2)(b)(ii)

The proposed change in clinical criteria would also align with revised guidelines (NZSSD) for prescribing. Pharmac staff consider this would likely capture that proportion of the population that would be impacted with removal of the ethnicity criterion in Phase 1. Staff consider Option 3 would demonstrate that while we would be removing the ethnicity criteria, that we are committed to assessing a wider group for future funding.

Why not the other options?

- Pharmac staff consider Option 1 would not be palatable amongst stakeholders.
- s 9(2)(b)(ii)
- We recognise there would likely be significant health benefit from widening access by lowering the CV risk threshold as per Option 2. However, given the s 9(2)(b)(ii) of widening access, staff consider it should be formally assessed and ranked on the OFI and progressed as its relative ranking and budget position allow. s 9(2)(b)(ii)
- While options 2 to 4 s 9(2)(b)(ii) the additional population covered do have a high health need and the proposal is still expected to be highly s 9(2)(b)(ii)
- Option 4 represents an approach that would likely be more publicly acceptable and aligns more closely with clinical advice. No change would be made prior to an implementation of widened clinical criteria for CVD risk. This option could substantially delay the removal of the ethnicity criteria and may not be acceptable for this reason.

8. Legal advice

s 9(2)(h)

s 9(2)(h) [redacted]

9. Plan for consultation on proposed approach

Section 70(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, Pharmac staff would take the following measures to inform the public, groups and individuals of that decision:

- prepare key messages to support consumer engagement and respond to any media queries
- communicate the decision with relevant key stakeholders, including health practitioners, clinicians and prescribers, CAC to ensure they are aware of the funded options and are able to support people starting the new treatments
- engage with key stakeholder groups (NZSSD, Diabetes NZ, Diabetes Network) and work together on communications that will be provided to their communities
- update the Pharmac website with relevant information and issue a media release if required
- notify all suppliers of the planned special authority changes through the usual Pharmaceutical Schedule processes.

Appendices

Appendix One	Record of Diabetes Specialist Advisory Committee (Final, unpublished)
Appendix Two	December 2023 Pharmac special authority check-up analysis
Appendix Three	Details about the Options
Appendix Four	Budget Impact Analysis for Options
Appendix Five	Special Authority proposed changes for Options