PHARMAC
TE PĀTAKA WHAIORANGA

# MEMORANDUM FOR PHARMAC BOARD MEETING

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| **To:** | Pharmac Directors |
| **From:** | Acting Director, Pharmaceuticals |
| **Meeting Date:** | 30 March 2026 |
| **Item:** | **5.3: Detailed analysis of removal of ethnicity criteria for diabetes medicines** |

## 1. 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 one of the following options:
  - ***Option 1:*** proceed to consultation to remove ethnicity criteria requirements from the special authority criteria for diabetes medicines and lower the five-year cardiovascular risk threshold from ≥15% to ≥10% (a person's chance of having a cardiovascular disease event in the next five years)

    ***note*** s 9(2)(b)(ii), s 9(2)(f)(iv), s 9(2)(g)(i), s 9(2)(i)

    s 9(2)(b)(ii) s 9(2)(b)(ii), s 9(2)(b)(ii), s 9(2)(f)(iv)

    ***note*** the proposed approaches in Option 1 would not impact those individuals who currently have access through the existing criteria and would only affect access for new individuals

  - ***Option 2:*** proceed to consultation on the above, only when there is sufficient budget to do so.
- ***note*** the estimated financials presented in this paper are based on current pricing assumptions and may be mitigated by future commercial initiatives.

## 2. Purpose

This paper seeks to inform the Board of Pharmac's assessment of the impact of removing ethnicity criteria from diabetes medicines and widening access by lowering the cardiovascular risk threshold criteria.

At its September 2025 meeting, the Board requested that the criteria for access to specific medicines for the treatment of type 2 diabetes (T2DM) better reflect Pharmac's strategic direction (see below) and that a paper be brought back to the Board, detailing Pharmac's assessment of the impacts from any potential changes to access.

## 3. Strategic Direction

The approach 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).

## 4. Executive Summary

Currently, access to two classes of diabetes medicines (SGLT2i and GLP-1a) 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 being at high risk of developing cardiovascular (CV) or renal (kidney) complications from diabetes.

Clinical advice was sought from the Obesity Treatments Advisory Group in December 2025, to understand what the impact on access to diabetes medicines through removal of the current ethnicity criteria and lowering the five-year CV risk threshold from ≥ 15% to ≥10% (five-year risk), would be.

The clinical advice we received indicates the proposed changes would likely enable most people who would derive significant health benefit to have access to these medicines (SGLT2i/GLP1a).

A full health economic analysis was undertaken to estimate the benefits and costs if Pharmac were to remove the ethnicity criteria and lower the CV risk threshold. This estimated an additional cost to the medicines budget of s 9(2)(b)(ii) (5-year NPV at 8%). Additionally, savings to the health system of approximately s 9(2)(b)(ii) (five-year NPV, 8% discount) would also be anticipated, due to reduced demand on health sector services from a reduction in hospitalisations.

The proposal to remove ethnicity criteria and lower the cardiovascular risk threshold has been ranked at s 9(2)(b on the Options for Investment List (as at March 2026). The cost-effectiveness of the proposed changes is estimated to be s 9(2)(b)(ii) QALYs per $ million, which is representative of very high-cost effectiveness.

## 5. Background and Context

The current Special Authority criteria for SGLT2i (empagliflozin, empagliflozin/ metformin) and GLP-1a (liraglutide, dulaglutide) medicines for type 2 diabetes, include 'Patient is Māori or any Pacific ethnicity' as an explicit key descriptor, defining access to treatment, without the need for other specific clinical criteria, apart from demonstrating poorly controlled T2DM.

In December 2020, the 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.

In 2025, in line with expectations from the Government about needs based service provision, Pharmac reviewed the ongoing need for specific ethnicity criteria in place for four funded medicines within the diabetes and cardiovascular therapeutic groups. Three of these medicines are the subject of this paper. The fourth is a cardiovascular medicine (statin), rosuvastatin. s 9(2)(b)(ii), s 9(2)(f)(iv), s 9(2)(g)(i), s 9(2)(i)

The Board requested at its September 2025 meeting, that staff provide additional analysis of the proposed option, specifically removing the ethnicity criteria and widening of access through changes to the clinical criteria for cardiovascular risk. The additional analysis that has now been completed includes a full health economic assessment of expanding eligibility to individuals with a cardiovascular risk of greater than or equal to 10% (versus 15% in the current criteria). This analysis has been completed and the proposed widening of access has been ranked as part of the March 2026 prioritisation process.

## 6. Summary of clinical advice received

Pharmac convened a meeting of the newly formed Obesity Treatments Advisory Group (OTAG) on 11 December 2025, to specifically provide clinical advice on the proposal to remove ethnicity criteria requirements from the special authority criteria for diabetes medicines and lower the five-year cardiovascular risk threshold from ≥15% to ≥10%. Although OTAG is a new group primarily formed to assess obesity-treatment-related proposals, members include several clinicians with an interest in the management of diabetes in both secondary and primary care settings and it was considered appropriate that this group consider the proposed changes.

The OTAG noted that:

- A proposed reduction in the CVD risk threshold from ≥ 15% to ≥10% would capture a substantial number of people who would derive significant health benefit from treatment with these medicines.
- Any change in criteria would only impact patients initiating treatment on these medicines. Patients with historical access would continue to have access, as the Special Authority is valid without renewal.
- Removing the existing ethnicity-based Special Authority criterion may introduce barriers to access for some Māori and Pacific people as it would require additional testing and health care visits.
- Any Special Authority criteria that did not require a full CVD risk assessment may not be in the best overall interests of a person with T2DM.
- If the ethnicity criteria were removed, many (but not all) individuals from these populations would still qualify under the other clinical criteria, such as the proposed reduction in CVD risk threshold to ≥10%.
- Māori and Pacific people diagnosed at a younger age would gain access via the existing ‘young adult’ criteria, noting that this is commonly defined as up to 40 years of age.

## 7. Budget Impact

A full health economic assessment has been undertaken for the proposed lowering of the five-year CVD risk threshold from ≥15% to ≥10%. Detailed information on the population living with diabetes was obtained from the Auckland University School of Population Health which contained information on the number of people with different CVD risk scores.

It is estimated that an additional 23,379 people with T2DM would meet the clinical criteria in the Special Authority due to the reduction in CVD risk score, with 43% (10,129) of those people initiating on one of the target diabetes medicines in the first year if funding was approved. This is based on the historical rate of uptake for these medicines.

The estimated cost to the pharmaceutical budget of this change in clinical criteria is s 9(2)(b)(ii) in the first full year and a five-year cost of s 9(2)(b)(ii) (NPV, 8%) (Table 1). There would also be estimated savings of s 9(2)(b)(ii) for the health system primarily due to a reduction in hospitalisation for the treated population.

s 9(2)(b)(ii), s 9(2)(f)(iv), s 9(2)(g)(i), s 9(2)(i)

For comparison, noting this was not requested by the Board in September 2025, if access was amended so that all people living with poorly controlled T2DM had the same access that Māori and Pacific people have in the current Special Authority criteria, the estimated cost to the medicines budget would be s 9(2)(b)(ii)

The population with a CVD risk score of 10–15% includes a substantial proportion (35%) of people of Māori or Pacific ethnicity. As a result, this threshold would capture a significant number of Māori and Pacific individuals with high health need who would otherwise have accessed treatment through the explicit ethnicity criteria in the Special Authority.

However, this change may also result in up to 7,000 fewer Māori and Pacific people becoming newly eligible for these diabetes medicines over the five-year period. This reflects the number of Māori and Pacific individuals who would still not meet the revised CV risk threshold or be eligible via other clinical criteria. Staff note the number is theoretical as we do not know how many Māori or Pacific people with a CV risk threshold of less than 10% are currently accessing treatment. In addition, it is possible that some may already be accessing treatment through other clinical criteria such as young onset diabetes, or presence of kidney disease.

**Table 1: Estimated Pharmaceutical Budget Impact of change in Special Authority Criteria (change in CVD risk from ≥15% to ≥10% and removal of ethnicity criteria)**

s 9(2)(b)(ii)

## 8. Prioritisation and Ranking

The proposal to remove ethnicity criteria and widen access through a change in the clinical criteria has been ranked at the March 2026 prioritisation meeting against other funding proposals on the Options for Investment list.

The analysis determined that the CUA value for this additional population (CVD risk score between 10% and 15%) was rated as s 9(2)(b)(ii) QALY's per $M). This was combined with a high health need score, and it has been ranked accordingly at s 9(2)(b)(ii) on the OFI. This elevated ranking highlights the proposed expanded clinical criteria as a high-value investment.

## 9. Factors for Consideration

### Health Need

Type 2 diabetes mellitus (T2DM) is a chronic disease categorised by high blood sugar levels (hyperglycaemia) that occurs as a result of insufficient production of insulin, the hormone that regulates blood sugar levels, or an ineffective response to the insulin the body produces. It is associated with severe long-term consequences, including microvascular complications such as neuropathy, retinopathy and nephropathy, and macrovascular complications such as CVD, stroke and heart failure. (World Health Organization, Global Report on Diabetes. April 2016). There are approximately 350,000 people in New Zealand living with T2DM; many of whom are at high risk of developing cardio-renal complications.

Of these, approximately 37% are of Māori or Pacific ethnicity. Indian and other south Asian ethnicities, who do not currently have access under the ethnicity criterion, represents another population in NZ experiencing health disparity due to a high prevalence of T2DM equating to 9% of total T2DM cases. There would likely be a positive impact to equity for this particular group if we were to lower the CV risk threshold to 10%.

Staff note there is uncertainty about the level of unmet health need among Māori and Pacific peoples who currently access treatment under the ethnicity criterion. This is because we do not have data on how many people gaining access through the ethnicity criterion would also be eligible under alternative clinical criteria.

While removing the ethnicity criterion could have a negative impact for Māori and Pacific people, the scale of that impact is uncertain. The lowered CV risk threshold of <10%, along with other eligibility criteria, such as young-onset diabetes and existing kidney disease, likely already capture many individuals who previously qualified under the ethnicity criterion.

### Health Benefit

SGLT2i medicines, such as the currently funded empagliflozin act by inhibiting glucose reabsorption in the kidneys, lowering blood glucose (measured by HbA1c levels). GLP1a medicines such as liraglutide and dulaglutide support glucose and appetite regulation by increasing insulin secretion and slowing gastric emptying. These medicines are used when other funded medicines for diabetes do not provide adequate control of blood glucose levels in people living with T2DM. Both medicine types have demonstrated health benefit by reducing the risk of complications in both the cardiovascular and renal areas, particularly for those people who are deemed at high risk of developing these types of complications.

### Suitability

Empagliflozin (SGLT2i) is medicine in tablet format and is also available in a combined formulation (with metformin), while liraglutide and dulaglutide GLP1a) are injectable medicines which are dosed daily and weekly respectively via a subcutaneous route. Both medicines are noted to be well tolerated with some minor issues during the initiation phase.

### Costs and Savings

The financial impact of this proposal to widen access to the medicines budget would be a cost of approximately s 9(2)(b)(ii) are expected due to reduced demand on health services primarily as a result of reduced hospitalisation for the complications of T2DM.

### Cost-Effectiveness

The cost-effectiveness of widening access to SGLT2i and GLP1a medicines via a reduced cardiovascular risk threshold (from ≥15% to ≥10% five-year risk) is estimated to be s 9(2)(b)(ii) The initial health economic analysis carried out prior to the initial funding decision in 2021 estimated cost effectiveness for SGLT2i of s 9(2)(b)(ii)

## 10. Risks and Mitigations

| Description | Mitigation |
|---|---|
| The risk of the new clinical description defining cardiovascular risk resulting in a population size greater than expected. Pharmac staff consider this as a low risk to the proposal. | This risk has been mitigated to a large degree through a thorough analysis of the diabetes registry and associated data sourced from the Auckland School of Population Health which holds detailed information on the numbers of people with diabetes and measured cardiovascular risk. |
| The risk of significant adverse public reaction to the removal of the existing ethnicity criteria as part of the proposed approach. Pharmac staff consider this risk as medium to high. | This risk would need to be mitigated by a thorough explanation of the approach at the point of consultation, identifying that current access would not be impacted, only future access. Also identifying that people at high risk would then receive access to these medicines, including other high-risk populations such as South Asian people, who have less access through the current criteria. |
| s 9(2)(i) | |

## 11. Appendices

Appendix One: Record of Obesity Treatments Advisory Group (Dec 2025) - draft

Appendix Two: Special Authority proposed changes for Options