PHARMAC
TE PĀTAKA WHAIORANGA

MEMORANDUM FOR PHARMAC BOARD MEETING

To:	Pharmac Directors
From:	Acting Director, Pharmaceuticals
Meeting Date:	28 April 2026
Item:	**3.3 Proposal to Proceed to Consultation to Amend the Special Authority 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 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)
- s 9(2)(b)(ii) [redacted]
- ***note*** the proposal would not impact those individuals who currently have access to diabetes medicines through the existing criteria and would only affect access for individuals new to treatment
- ***note*** the proposed changes to the special authority criteria align with other similar instances across the health sector where such changes to remove ethnicity-based criteria have occurred.

2. Purpose

This paper seeks the Board's approval to proceed to consultation on removing ethnicity-based eligibility criteria from funded diabetes medicines and widening access through a lower cardiovascular risk threshold. The paper also provides context on comparable NZ health sector precedents where ethnicity criteria have been withdrawn and replaced with alternative access settings.

At its March 2026 meeting, the Board requested that Pharmac staff provide clarity on:

- how the proposed changes to the special authority criteria for diabetes medicines align with what is occurring elsewhere across the health sector.
- the financial impact to the medicines budget of the proposed amendments to the eligibility criteria for funded diabetes medicines.
- the rationale for the proposed approach to ethnicity criteria, including operational and system considerations.

3. Strategic Direction

The proposed 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 the Pae Ora (Healthy Futures) Act 2022 (the Act).

4. Executive Summary

The Board previously considered options in December 2025 and March 2026 for the removal of existing ethnicity-based criteria on two categories of diabetes medicines (SGLT2i and GLP1a) and replacement with amended clinical criteria (lowering the five-year cardiovascular risk threshold from ≥15% to ≥10%) effecting widened access.

Analysis has been undertaken that demonstrates the estimated financial impact of implementing the preferred option would be a five-year cost of s 9(2)(b)(ii)

s 9(2)(b)(ii)

The rationale for proposing this change in the clinical criteria is based on the same approach as used in examples across the health sector, with a widening of universal access based on measurable, evidenced, clinical criteria. This approach may not capture the entire population defined by the current ethnicity criteria but will target those most likely to derive significant clinical benefit.

The current ethnicity criteria for diabetes medicines also places us at risk of legal challenge and complaints of various natures, which Pharmac has already received. For context, the use of age-based criteria in this context also carries similar risk. Removal of such criteria would minimise this risk and would be aligned with Government direction on needs-based service provision.

Three examples of similar changes from across the health sector are described below. These demonstrate it is feasible to replace specific ethnicity criteria with other clinical risk identifying measures. Two of the examples are previous Pharmac decisions (influenza vaccines and COVID-19 therapeutics) while the other relates to a Health NZ bowel screening initiative. These represent the most comparable instances of amending access criteria with the removal of an ethnicity-related component and demonstrate that the current proposal is in line with others across the sector.

Importantly, the proposed approach outlined for diabetes medicines would preserve access for those people currently receiving treatment with these medicines because of the ethnicity criterion. No people currently accessing these medicines would be disadvantaged.

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 type 2 diabetes management.

At its December 2025 meeting the Board considered potential alternative access criteria for SGLT2i medicines. The access criteria considered by the Board were subsequently taken for expert advice to Pharmac's Obesity Treatments Advisory Group in December 2025. Following a health economic evaluation the Board considered the economic assessment at its March 2026 meeting.

At its March 2026 meeting, the Board requested additional information regarding similar cases in the health sector where there has been a change from ethnicity criteria to more explicit needs-based criteria. The Board also requested additional information on how proceeding with the proposal would impact the current medicines budget position, and more commentary on the rationale for the proposed approach to ethnicity criteria, including operational and system considerations.

6. Examples of other health sector changes in ethnicity-based criteria

There are several examples in the health sector where ethnicity-based access criteria have recently been amended. The approach used in the current proposal for diabetes medicines is consistent with that identified in the listed examples, principally the concept that no patients who have had access to the medicines through the ethnicity criteria will lose that access through any amendment to the special authority. The specific examples are as follows:

a) National Bowel Screening Programme (NBSP)

Funding was redirected from a targeted Māori/Pacific age-50 pilot approach to lowering the universal eligibility age from 60 to 58 years (58–74), phased in regionally from October 2025 to March 2026.

The NBSP was originally rolled out nationally from July 2017 with access criteria that included all people between the ages of 60-74 using test kits every 2 years, to do self-testing at home. Policy direction and pilot work had been undertaken that aimed to lower the free bowel screening eligibility age for Māori and Pacific peoples to 50 years. From 2022, three pilot districts Waikato/ Tairawhiti/ Midcentral introduced access for Māori and Pacific people from the lower age of 50.

In March 2025, the Government announced that funding previously set aside for the Māori/Pacific age-50 approach would be redirected to lower the universal eligibility age from 60 to 58 (with a 58–74 age band), to be phased in regionally from October 2025 in two regions, and March 2026 in the remaining regions.

Those people that qualified for screening under the Māori/Pacific focused pilot programme would continue to be eligible for access to screening every 2 years; however, new entrants would need to be aged 58-74 years.

b) Funded Seasonal Influenza (Flu) Vaccination

Automatic funded access for Māori and Pacific peoples aged 55–64 was removed, with eligibility reverting to universal age and clinical risk-based criteria for the 2024 'flu' season onwards.

As a result of additional "ring-fenced" COVID-19 funding, Pharmac widened funded access to the influenza vaccine during 2022/23 so that all Māori and Pacific people aged 55–64 years could receive a funded seasonal flu vaccine. Other populations could access the funded vaccine if aged 65 or older, or if people had a specified long-term condition, or were pregnant, or experienced mental health conditions.

From the 2024 season, Pharmac confirmed the specific funding used to support those expansions had ended; therefore, Māori and Pacific people aged 55–64 years were no longer automatically eligible (unless they met other access criteria).

This was an example of an explicit shift from ethnicity-based access (age 55–64 and Māori/Pacific) to clinical risk/age-based criteria, noting that this was always envisaged as a short-term measure.

c) COVID-19 antiviral access

Eligibility shifted from ethnicity-based age thresholds to a universal, clinician-assessed risk criteria for people aged 50 years and over, effective September 2025.

During the earlier phases of COVID-19 antiviral access, there was an explicit policy intent to increase access for Māori and Pacific people via different age thresholds, described in the literature as ≥50 years for Māori/Pacific vs ≥65 years for other ethnicities (when comorbidity/vaccination criteria weren't met). This earlier access for Māori and Pacific people (reduced age) was implemented in September 2022.

From September 2025, funded access to COVID-19 antivirals was widened so that all people aged 50 years and over with COVID-19 would qualify where their health professional considers them at high risk of hospitalisation or death, introducing explicit clinician discretion to capture risk factors not otherwise specified in the criteria.

This widened access replaced the previous criteria which provided access at a younger age (≥50 years) for Māori/Pacific ethnicity and/or not having completed a primary COVID-19 vaccination course, rather than clinician judgement for "other" risk drivers. Eligibility for people aged 65 years without other risk factors remained unchanged.

This approach is an example of moving from explicit ethnicity-based eligibility criteria (different age thresholds) to a universal "risk-based" gateway (age 50+ and assessed high risk), while still allowing clinicians to consider risk factors. The proposed approach with regard to diabetes medicines would employ a similar widened risk threshold.

7. Rationale for the current proposal for diabetes medicines

Moving from ethnicity-based criteria to a reduced clinical risk threshold (CVD risk threshold reduced from current "≥15%" to "≥10%").

The rationale for proposing this change in the clinical criteria is based on the same approach as in the other examples noted above, with a widening of universal access based on measurable, evidenced, clinical criteria. This approach may not capture the entire population defined by the current ethnicity criteria but will target those most likely to derive significant clinical benefit. Importantly, as with the NBSP example, no current patients would lose access, the change in criteria would apply only to new patients.

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 primary care and secondary 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 type 2 diabetes management.
- 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, in clinical practice, as up to 40 years of age.

8. Legal Advice – Legally Privileged

s 9(2)(h)

9. Budget Impact

The estimated cost to the medicines budget of these changes to the criteria is s 9(2)(b)(ii)

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

	Year 1	Year 2	Year 3	Year 4	Year 5	5 Yr NPV
Additional Patients	10,129	2,724	3,094	3,497	3,934	23,379
Pharmaceutical Expenditure (Net)	s 9(2)(b)(ii)					
Health Sector Costs (Offset)						
Total (Net Impact)						

Following the March 2026 Board meeting, Pharmac received confirmation from s 9(2)(b)(ii)

s 9(2)(b)(ii)

Assuming a 1 August 2026 listing, progressing this proposal in the absence of any additional medicines budget uplift would somewhat worsen the equity position in 2028/29 and 2029/30 (by s 9(2)(b)(ii) and s 9(2)(b)(ii), respectively). However, it would not materially impact the overall trend and position of the medicines budget.

10. 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.

s 9(2)(b)(ii)

11. Factors for Consideration

Health Need

Type 2 diabetes mellitus (T2DM) is a chronic disease categorised by high blood sugar levels. 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. (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 proposed lowered CV risk threshold of ≥10%, along with other eligibility criteria, such as young-onset diabetes and existing kidney disease, would likely 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 from reduced hospitalisation for 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)

12. 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 risk to be low.	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 if existing ethnicity criteria are not removed. Pharmac has recently received a number of enquiries citing concern with ethnicity criteria, requiring significant staff time to address and respond to. Pharmac staff consider this risk as medium to high.	Progress to consultation on proposed criteria changes.
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 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)	s 9(2)(i)

13. Appendices

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

Appendix Two: Special Authority proposed changes for Options