

The logo for PHARMAC (Te Pātaka Whaioranga) is a white circle containing the text "PHARMAC" in a bold, sans-serif font, with "TE PĀTAKA WHAIORANGA" in a smaller, all-caps, sans-serif font below it. The logo is positioned on the left side of the slide, overlapping a decorative graphic of teal wavy lines.

PHARMAC
TE PĀTAKA WHAIORANGA

Diabetes Advisory Committee meeting 26 June 2025

**SGLT2i and GLP-1a Special Authority
Criteria – Review**

Review context

- The purpose of this review is to determine whether the current Special Authority criteria as listed in the Pharmac Schedule for access to SGLT2i (empagliflozin and empagliflozin with metformin) and GLP-1a (dulaglutide and liraglutide), which contain specific ethnicity-based aspects, remain appropriate.
- There is a need to ensure that the criteria are consistent with the main policy items in relation to Pharmac's operations, notably :

- **The 2024-2025 (Pharmac) Letter of Expectations**
- **The Cabinet Circular of 13 September 2024, titled Needs-based Service Provision.**
- **Section 6 and Section 7 of the Pae Ora (Healthy Futures) Act 2022.**
- **The Government Policy Statement on Health 2024-2027**



The purpose of this meeting is to understand how we can ensure preserved access for those people with the target health need through the Special Authority and other clinical criteria.



Background

- Specific ethnicity criteria targeting Māori and Pacific people was incorporated into the special authorities for SGLT2i and GLP1a following consultation feedback in 2020.
- Intent of inclusion of ethnicity criteria was to attempt to address the disproportionate health burden of diabetes for the Māori and Pacific populations and overcome barriers to access.
- The final criteria waived the additional requirement for definitive clinical evidence of cardiorenal disease or risk if the person was of Māori or Pacific ethnicity
- There is a need to define target patient populations in special authority restrictions using clinical criteria as a priority over other demographic identifiers (e.g. ethnicity / age)

Health need - Target Population

- Target for funding - *People with T2DM at high risk of cardiovascular and renal complications where glycaemic control has not been achieved using first-line agents.*
- 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.
- We know:
 - Māori and Pacific adults are more likely to have type 2 diabetes compared with other ethnic groups, and 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.

Questions to the 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?

Potential criteria (GLP1a)

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

Potential Criteria (SGLT2i)

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.

Questions to the Committee

Special Authority criteria

- 1) 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. How do our current SA criteria align or not align with this tool and any other tools used in clinical practice in NZ?

- 2) If possible, how would the criteria best be amended to ensure that those Māori or Pacific people who currently can access SGLT_i / GLP-1a medicines via the ethnicity criteria would still be able to do so in the future?
 - a. Noting proposed amends, do the potential criteria preserve access to the currently funded patient group?
 - a. If not, 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?

Questions to the Committee

Costs and Savings

- 1) How would the changes as described impact access to and use of SGLT2i / GLP-1a medicines ?
 - a. To what degree would usage change for Māori / Pacific people with T2DM?
 - b. To what degree would usage change for anyone with T2DM at risk of cardio-renal complications?

Other

- 1) Do you have any additional comments?



**- Recommendations regarding
changes to criteria -**