P-002206 SGLT2i followed by GLP-1RA as required - Type II diabetes, moderate five-year CVD risk

GENERAL

Latest Clinical Recommendation:

- Obesity treatments Advisory Group (December 2025, Objective File: A1976779) made no formal recommendation regarding the revised PICO.

Condition: Type two diabetes mellitus (T2DM) with a five-year cardiovascular (CVD) risk of 10-<15% and an HbA1c above target despite treatment with standard of care, not covered by existing Special Authority criteria

Comparator: Standard of care for diabetes (eg metformin hydrochloride, vildagliptin, or glibenclamide, and injected insulin preparations).

Availability of existing alternatives: Current medications for T2DM include oral hypoglycaemic agents such as metformin hydrochloride, vildagliptin, or glibenclamide, and injected insulin preparations.

NEED

Health need of the person: 10 (Moderate)

The following is taken from Pharmac's Diabetes Health Need Statement reviewed by PTAC in May 2018 (Objective ID: A1126223):

T2DM is a chronic disease categorised by high blood sugar levels (hyperglycaemia). Hyperglycaemia occurs as a result of insufficient production of insulin, the hormone that regulates blood sugar level, and an ineffective response to the insulin the body produces (WHO, 2016). The disease is associated with severe long-term impacts including microvascular consequences such as neuropathy, retinopathy and nephropathy, and macrovascular consequences including cardiovascular disease, stroke and heart failure.

People with T2DM are often initially unaware of any symptoms though overtime can develop severe comorbidities and die prematurely of the disease. Sustained lack of control of diabetes can increase the risk of complications including cardiovascular disease, retinopathy, neuropathy and nephropathy which are associated with a significant loss in quality and quantity of life. The risk of developing diabetes complications is reduced with good blood pressure, blood glucose and blood cholesterol control but increases with diabetes duration.

The Sodium Glucose Transport Protein-2 inhibitors (SLGT2i), such as empagliflozin, are proposed as an adjuvant second-line therapy to an existing treatment regimen. Glucagon-like peptide-1 (GLP-1) receptor agonists (RA), such as dulaglutide and liraglutide, are proposed as a fourth line adjuvant therapy following insufficient benefit from three previous treatment options (including SLGT2i).

Note, SGLT2i and GLP-1 RA are already funded for people with an absolute 5-year CVD risk of ≥15%, established CVD, chronic kidney disease, or an elevated lifetime risk of comorbidities due to being diagnosed at a young age. This proposal is for people with a lower 5-year CVD risk (≥10%) who do not meet other Special Authority criteria.

Health Need of Family, Whānau and Others: As above, long-term sustained uncontrolled management of diabetes is associated with a range of severe complications and premature death. This has a significant impact on family and whānau who may have to care for the person

with diabetes-related complications, or those around them (tamariki), and who will experience the premature death of the person with T2DM.

Māori Health Areas of Focus: Diabetes (Matehuka) | Heart Health - High Blood Pressure & Stroke (Manawa Ora)

Māori health need: In 2023, Māori made up 21.5% of the total population with T2DM and a 5-year CVD risk of 10-<15% (Auckland University Database: Objective ID: A1978254). Statistics NZ reported that in 2023, those identifying as Māori made up 10.6% of the 65-69 age group (the mean age of those in the Pharmac economic assessment was 65 years) (Stats NZ). This suggests that Māori may be twice as likely to be in this patient population.

Māori experience a disproportionately higher burden of diabetes and diabetes complications compared to non-Māori (Mustafa et al, Diabetology, 2026;7:12). The Atlas of Healthcare Variation found that across all age groups, Māori had higher rates of admissions for diabetes-related complications, such as diabetic ketoacidosis, hypoglycaemia and lower-limb amputations (HQSC. Atlas of Healthcare Variation: Diabetes. 2024).The onset of diabetes occurs at an earlier age for Māori and the progression to diabetes complications is more rapid, particularly for renal failure (Perera et al, Diabetes Res Clin Pract, 2026;231:113018). Māori also experience higher premature mortality as a result of diabetes and cardiovascular disease (Yu et al, Lancet Glob Health, 2021;9:e209-217).

The Diabetes Advisory Committee (June 2025) considered that removing the Special Authority criteria granting access to SGLT2i and GLP-1 RA based on Māori ethnicity will reduce access for this population (Objective ID: A1976760). As per 7.13 of the OTAG record, December 2025, many (but not all) Māori would still qualify under other measures, such as the lower CVD risk threshold (≥10%) assessed here, and existing criteria (the established CVD, chronic kidney disease, or high lifetime risk due to being diagnosed with T2DM in childhood or as a young adult). However, the removal of ethnicity-based criterion is considered to introduce barriers to access for Māori, such as additional testing and healthcare visits (OTAG, Dec 2025: record 7.16).

In 2023, of the people with T2DM being treated with SGLT2i (with and without other drugs), 23.1% were Māori. Of those being treated with GLP-1 agonists (with and without other drugs), 32.3% were Māori (Auckland University Database Objective ID: A1978254). The higher rate of Māori access to SGLT2i and GLP-1 RA compared with the proportion of Māori with T2DM may suggest an absence of barriers to access to these treatments currently. This may support the Committee's consideration that removing the ethnicity criterion may create a barrier to access.

Impact on population groups experiencing disparities:
Pacific People
Auckland University data showed that in 2023, Pacific People made up 15.4% of the population with T2DM and a 5-year CVD risk of 10-<15% (Auckland University Database Objective ID: A1978254). Statistics NZ reported that in 2023, those identifying as Pacific made up 4.0% of the 65-69 age group (the mean age of those in the Pharmac economic assessment is 65 years) (Stats NZ). This suggests that Pacific people may be around three times more likely to experience this condition.

In 2023, of the people being treated with SGLT2i (with and without other drugs), 21.5% were Pacific peoples. Of those being treated with GLP-1 agonists (with and without other drugs), 12.2% were Pacific peoples (Auckland University Database Objective ID: A1978254). The higher rate of Pacific people's access to SGLT2i compared with the proportion of T2DM that are Pacific people supports the Committee's consideration that removing the ethnicity criterion may create a barrier to access.

Other groups experiencing disparity in T2DM burden
The Virtual Diabetes Register reports that people of Indian ethnicity had the second highest estimated age-standardised diabetes prevalence in 2024 at 10.3% and a higher rate of disease

complications (crude measure not found)(Diabetes Register, 2024). Per 6.16.7 of the Diabetes Advisory Committee record, May 2025, although South Asian ethnic groups were at higher risk of type 2 diabetes compared with other groups, in contrast to Māori and Pacific people, systemic barriers and outcomes disparities did not appear to be as significant (Chan et al. Counties Manukau Health, 2020).

People living in areas of low socioeconomic status are also noted to have a higher diabetes/CVD disease burden (Diabetes Register, 2024).

Government condition priorities: Access | Non-communicable diseases: diabetes

HEALTH BENEFITS

Health benefit to the person: SGLT2i medicines, such as empagliflozin, act by inhibiting glucose reabsorption in the kidneys, consequently lowering blood glucose (measured by HbA1c levels).

GLP-1 RA medicines, such as dulaglutide and liraglutide, support glucose and appetite regulation by increasing insulin secretion and slowing gastric emptying. The result is reduced food intake and an increased sense of satiety.

Of relevance to this proposal is a 2021 systematic reveiew and network meta-analysis of randomised controlled trials comparing SGLT-2 inhibitors or GLP-1 RAs with placebo, standard care, or other glucose lowering treatment in adults with T2DM (Palmer et al. BMJ. 2021;372:m4573). The study stratified results by CVD risk category. Per 7.5.4 of the meeting record, December 2025, OTAG noted that the risk categories do not directly align with those applied in the New Zealand context, but that the "low-risk with more than three risk factors" category in the analysis likely best reflects the baseline risk of a population with a ≥10% 5-year CVD risk. Based on this assumption, OTAG considered that individuals with a 10-<15% 5-year CVD risk would be expected to derive significant health benefit from access to these medicines.

The study indicated that, for the 'low risk' group over five years, SGLT2i was associated with an approximate 14% reduction in all cause mortality, 10% reduction in CVD events and a 33% reduction in kidney failure compared to placebo. GLP-1 RA was associated with an approximate 11% reduction in all cause mortality, 10% reduction in CVD events, and 17% reduction in kidney failure compared to placebo (Palmer et al, 2021). While the 'low-risk' category in this study did not directly correlate to the proposal population (5-year CVD risk of 10-<15%), these study results were used to estimate health benefit.

The undiscounted QALY gain over a lifetime time horizon, for an SGLT2i followed by a GLP-1 RA when required relative to standard of care was 0.13 QALYs.

Health benefit to family, whānau, others: Extending survival and reducing the likelihood of poor outcomes from diabetes such as renal disease were considered highly likely to benefit family and whānau.

Consequences for health system: An SGLT2i followed by a GLP-1 RA when required was expected to reduce the frequency of hospitalisations from CVD events and renal replacement, therapy representing a cost saving to the health system. Better control of diabetes in general may also decrease some health service utilisation.

Government system priorities: Health equity

COSTS AND SAVINGS

Health costs to the person: To access SGLT2i and/or GLP-1 RAs, individuals must be able to reach a general practitioner (GP) and blood-testing clinic to complete a CVD risk-assessment and receive a prescription. They will therefore incur the costs associated with these activities.

Health costs to family, whānau, others: None identified.

Pharmaceutical costs per person: Pharmaceutical costs are ongoing and in addition to existing treatments. An SGLT2i is estimated to cost s 9(2)(b)(ii) per month. A GLP1 RA is estimated to cost s 9(2)(b)(ii) per month based on the market share of dulaglutide to liraglutide. Both of these estimates are based on confidential net pricing.

Costs to rest of health sector, per person: The use of SGLT2i and GLP-1 RA are likely to result in savings to the health system as a result of a reduction in heart failure hospitalisations and initiations of renal replacement therapy.

There are health system resource costs associated with the full CVD risk assessment required for prescription.

SUITABILITY

Impact on use by the person: Empagliflozin is an oral tablet taken once per day.

Dulaglutide is a self-administered injection with a prefilled pen once per week. It is administered in addition to existing treatment.

Liraglutide is a self-administered subcutaneous injection with a prefilled pen once daily. It is administered in addition to existing treatment.

Impact on use by others: Current SGLT2i and GLP-1 RA options are not expected to be administered by family, whānau or others.

Impact on health workforce: A full CVD risk assessment would be required prior to SGLT2i or GLP-1 RA prescription.

COST-EFFECTIVENESS

Point estimate: s 9(2)(b QALYs per $1m

s 9(2)(b)(ii) QALYs per $1m s 9(2)(b)(ii)

CUA notes: The cost utility is most sensitive to assumptions about the efficacy of an SGLT2i and a GLP-1 RA.

BUDGET IMPACT

BIA notes: It is estimated that there will be 10,129 new patients starting treatment in the first year of listing, and 3,934 patients starting treatment per year by year 5.

It is assumed that uptake will be 60% in the first year, and 100% in year 5. This is based on the pattern of uptake of an SGLT2i in those with T2DM.

While the budget impact is cost saving to the health sector over five years an SGLT2i followed by a GLP1 RA when required is expected to incur a cost to the health system over an individuals lifetime.

Year	1	2	3	4	5	5-year NPV
Patients	10129	2724	3094	3497	3934	-
Pharmaceutical costs	s 9(2)(b)(ii)					
Other health sector costs	-$1,306,605	-$4,078,828	-$7,013,075	-$10,179,076	-$13,607,054	-$29,177,949
Total health sector budget impact	s 9(2)(b)(ii)					