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1. Budget Impact Analysis

1.1. Patient numbers

Patient numbers were estimated using a New Zealand database containing relative CVD risk profiles for people with diabetes, stratified by relevant subgroups. This information was provided to Pharmac staff by researchers at the University of Auckland (see Section 5.1.2.1). This data was supplemented with additional New Zealand data sources and published literature to refine the estimates.

No data was available for the proportion of people with diabetes in New Zealand who have T2DM. Australian estimates suggest that T2DM accounts for 87% of all diabetes in adults (Australian Bureau of Statisitics. Diabetes. Released December 2023). It was assumed that 90% of people with diabetes in New Zealand had T2DM as a conservative estimate.

The estimated population included people with T2DM and a CVD risk of 10 to <15% whose HbA1c was above target, excluding those with:

- CKD (defined as: persistent albuminuria and/or eGFR less than 60 mL/min/1.73m^2 in the presence of diabetes, without alternative cause),
- Established CVD, or
- A lifetime elevated risk of CVD due to being diagnosed with T2DM at a young age (before the age of 40).

The prevalent population estimates exclude Māori and Pasifika people with a CVD risk of 10 to <15% who are currently accessing treatment. The incident population includes all those who would gain access under the proposed Special Authority, as well as Māori or Pacific peoples who meet the new access criteria and are not currently accessing treatment.

1.1.1 Population growth over time

To estimate the size of the population beyond the database date (2023) it was assumed that the growth in the number of people with T2DM would follow the same rate as the increase observed in the overall diabetes population. Using annual data from the Virtual Diabetes Register, the diabetes population were found to be increasing by an average of 6.21% per year over the last three years (Health New Zealand Virtual Diabetes Register Web tool. Last Accessed February 2026).

1.1.2 Proportion eligible for treatment

The proportion of people that would gain access to treatment through this proposal is outlined in Table 19 below. In includes the T2DM population with a 5-year CVD risk of 10-<15% who do not have established CVD or CKD, were not diagnosed under the age of 40 (youth diagnosis), and do not meet target HbA1c despite treatment.

Table 1. Proportion of those with T2DM that would gain access to treatment

Parameter	Proportion of those with T2DM	Source
(A) Proportion with 5-year CVD risk of 10-<15%, including slippage from those with a risk of 5-<10% (no CVD)	17.48%	Auckland University data (See 'Number of pts with DM' sheet in Objective ID A1978502)
(B) Proportion without CKD	80.00%	See Section 5.1.3.2
(C) Proportion not diagnosed with early onset T2DM	90%	See Section 5.1.2.2
(D) Proportion with an HbA1c above target	53.70%	Proportion above target (Mustafa et al. 2026)
Total proportion of T2DM population eligible under this proposal	4.79%	A x B x C x D minus Māori and Pacific peoples already on treatment

It was assumed that those with a five-year CVD risk of 10-<15% were proportionally as likely to have youth-onset T2DM or an HbA1c above target as the overall of the T2DM population. Specifically, it was assumed that having a 10-<15% five-year risk did not make individuals more or less likely to have been diagnosed under the age of 40 or have an HbA1c above target.

This is supported by results from a study on CVD risk prediction in Chinese people with T2DM which reported that age at diagnosis was not an independent factor of higher or lower 10-year CVD risk (Yao et al. Endocrinol. 2023;14). Similar results were reported in a Belgian retrospective analysis which found no significant increase in CVD events in those with youth diagnosis compared to people diagnosed at an older age over the same period of time since diagnosis (Deconinck et al. Diabetology & Metabolic Syndrome. 2017;9:28).

1.1.2.1 Proportion of people with a 5-year CVD risk of 10-<15% (no CVD) plus slippage

This estimate was derived from the Auckland University dataset, which includes the Virtual Diabetes Register population as of 1 January 2023 and covers New Zealanders aged 30–79. Individuals' data was stratified by five-year CVD risk groups (<5%, 5 to <10%, 10 to <15%, and ≥15%) and presented separate to those with established CVD. The data was further broken down by 10-year age bands and by ethnicity (Māori, Pacific peoples, and non-Māori/non-Pacific). The data provided to Pharmac staff can be viewed here: Objective ID A1978254. This proportion of people with a five-year CVD risk of 10 ≤ 15% was estimated to be 15.3% of the total T2DM population.

Some allowance for "slippage" was also included, reflecting the inherent imprecision of the PREDICT tool used to estimate CVD risk in New Zealand. Values close to a threshold (for example, 9.5% vs 10%) can reasonably be treated as equivalent (Internal modelling meeting, Objective ID A1988117). Accordingly, it was assumed

that 10% of people with a 5–<10% CVD risk may also receive SGLT2 inhibitors if funded, adding a further 2.2% of the T2DM population.

Overall, the estimated proportion of people with a 5-year CVD risk of 10–<15% (without established CVD), including slippage, was estimated as 17.5%.

1.1.2.2 Proportion who was not diagnosed during childhood or youth

In this assessment, patients diagnosed with T2DM during childhood or as a young adult (as specified in Special Authority criteria) was defined as those diagnosed with T2DM under the age of 40 (OTAG December 2025).

The proportion of people with early onset T2DM was estimated using Special Authority approvals for an SGLT2i who had met the criterion “patient has a high lifetime CVD risk due to being diagnosed with type 2 diabetes during childhood or as a young adult” (Pharmac Qlik Special Authority Dispensing Summary, Application Chemical SGLT2 inhibitors). The number of these approvals over time was compared to the number of Special Authority approvals for an SGLT2i with the input “Patient has type 2 diabetes.” This consistently represented approximately 10% of individuals across the years of available data.

Youth diagnoses (diagnosis before age 40) was therefore estimated to account for 10% of all T2DM diagnoses in the analysis. It was assumed that individuals diagnosed before age 40 were uniformly distributed across the T2DM population, and therefore proportionally represented within the 10–<15% CVD-risk group.

Although youth-onset T2DM may comprise a higher share of the younger T2DM population due to elevated lifetime CVD risk, potential earlier mortality, and increasing rates of youth diagnoses a conservative assumption of equal proportional representation was applied to avoid overestimating the number of people who would already qualify for treatment under the youth-diagnosis criterion

In addition, it was noted that Māori or Pacific peoples accessing treatment through the ethnicity criterion may also have met the early-onset criterion. Therefore, it is unclear if the removal of the ethnicity criterion may increase the proportion of people that will gain access to treatment through the early onset criterion.

1.1.2.3 .Proportion who does not have CKD

The proportion of people with CKD was estimated based on a worldwide systematic review and meta-analysis which reported that 27% of people with T2DM had CKD (Fenta et al. Diabetol Metab Syndr 2023;15:245).

This estimate was higher than the prevalence observed in RCTs enrolling participants without established CVD - for example, 7.4% in DECLARE-TIMI 58 (dapagliflozin) (Mosenzon et al. Lancet Diabetes Endocrinol. 2019 Aug;7(8):606-617) and 15.6% in SAVOR-TIMI 53 (sitagliptin) (Scirica et al. N Engl J Med. 2013 Oct 3;369(14):1317-26). However, both trials excluded patients with severe renal impairment so these lower figures were not considered representative of the broader T2DM population.

Therefore, the estimate reported by Fenta et al (2023) was considered the most appropriate benchmark, although CKD prevalence was expected to be lower in

population with lower CVD risk. Accordingly, the proportion of individuals with T2DM who also have CKD was set at 20%.

It was assumed that those with early onset T2DM would experience CKD at the same rate as the average T2DM population.

To avoid double counting, individuals diagnosed with CKD before age 40 and who also had a five-year CVD risk of 10–<15% were removed from the count of people with CKD in the 10–<15% risk group.

1.1.2.4 Proportion with an HbA1c above target despite treatment

A New Zealand study on ethnic inequities in glycaemic targets in T2DM was used to estimate the proportion of people with an HbA1c above target (Mustafa et al. Diabetology. 2026;1:12). The study reported that 53.7% of individuals with T2DM in New Zealand had an HbA1c above the recommended target.

1.1.2.5 Māori and Pacific people already accessing SGLT2i or GLP1 RA

A prevalent population was defined as the eligible population that had not previously accessed an SGLT2i. People with T2DM of Māori or Pacific ethnicity would have been eligible for treatment under previous Special Authority criteria, and therefore many would have already accessed treatment. To estimate this, the proportion of Māori or Pacific peoples who had already received an SGLT2i by the end of 2025 was calculated based on initial Special Authority approvals for empagliflozin and empagliflozin with metformin (Pharmhouse. Special Authority Dispensing Summary (Application type [initial], Dispensed chemical [empagliflozin, empagliflozin with metformin, SGLT2 inhibitors]). Accessed via Qlik February 2026) and comparing these with the number of Māori or Pacific peoples with T2DM. This indicated that 76% of Māori or Pacific peoples had received an SGLT2i by February 2026. Therefore, 76% of Māori or Pacific peoples in the prevalent population were excluded from those estimated to newly gain access, as they were assumed to have already received treatment.

People of all ethnicities were included in the incidence population. It is possible that the incidence population calculations are an overestimate, as they may include people of Māori or Pacific ethnicity who have accessed treatment via the ethnicity criteria while they had a CVD risk of <10% but have since progressed to 10-<15%.

1.1.2.6 Overall proportion of T2DM gaining access to an SGLT2i with the Special Authority change

Based on the above assumptions, amending the Special Authority criteria to include people with a 10 to <15% five-year risk of CVD will allow an additional 4.79% of the T2DM incident population to access SGLT2i and GLP1 RA treatment. This represents a prevalent group of approximately 16,900 people and an incidence of approximately 3,500 additional people eligible each year.

1.1.3 Uptake

Uptake was assumed to be 60% in year one increasing to 100% by year five. This was informed by Qlik data on the cumulative number of patients who had accessed an SGLT2i since funding (Pharmac Qlik, Special Authority Dispensings. Application

Chemical SGLT2 inhibitors, empagliflozin, empagliflozin with metformin. Dispensed calendar year Application type initial, inputs, patient has type 2 diabetes) compared to an approximation of the eligible population. The approximation was based on the same method as is outlined in Section 5.1.2. These data showed a pattern of increasing uptake over time.

It was considered reasonable to assume that uptake in year one would be 60% as this is a treatment that clinicians are familiar with prescribing for a similar patient population.

1.2. Costs

Pharmaceutical and treatment costs per person, each year for the first five years of the model time horizon, either under status quo or with the proposal, are drawn directly from the cost-utility model. These figures are in the budget impact analysis workbook, Objective ID A1978502, tab: “BIA”

1.3. Results

The budget impact (five-year net present value (NPV)) to the Combined Pharmaceutical Budget (CPB) of funding an SGLT2i followed by a GLP1 RA when required is estimated to be s 9(2)(b)(ii), with a cost in the first 12 months of s 9(2)(b)(ii). This is outlined in Table 20 below. The budget impact (five-year NPV) to health systems is estimated to be s 9(2)(b)(ii) All costs are discounted at a rate of 8% per year.

Table 2. Net Budget Impact to health systems

Funding year	Year 1	Year 2	Year 3	Year 4	Year 5	5-Year NPV
Patients initiating treatment	10,129	2,724	3,094	3,497	3,934	-
Net impact on pharmaceutical budget	s 9(2)(b)(ii)					
Net impact on non-pharmaceutical health system costs	-$1,306,605	-$4,078,828	-$7,013,075	-$10,179,076	-$13,607,054	-$29,177,949
Total net budget impact to health system	s 9(2)(b)(ii)					