

## 9.01 SGLT2 inhibitors for the treatment of type 2 diabetes

### DAPAGLIFLOZIN

### DAPAGLIFLOZIN WITH METFORMIN

Forxiga<sup>®</sup>, Xigduo XR<sup>®</sup>

### ASTRAZENECA PTY LTD

### EMPAGLIFLOZIN

### EMPAGLIFLOZIN WITH METFORMIN

Jardiance<sup>®</sup>, Jardiamet<sup>®</sup>

### BOEHRINGER INGELHEIM PTY LTD

## 1 Purpose of Item

That the PBAC:

- 1.1 **Provide advice** on the updated assumptions and inputs underpinning the revised financial impact to the Repatriation/Pharmaceutical Benefits Scheme (R/PBS) associated with expanding the listings for sodium-glucose cotransporter 2 (SGLT2) inhibitors (dapagliflozin and empagliflozin, including combinations with metformin) in line with the March 2022 PBAC recommendation to include treatment of patients with type 2 diabetes mellitus (T2DM) and established cardiovascular disease (CVD) or high cardiovascular (CV) risk, as add-on therapy to metformin, without a glycaemic requirement.
- 1.2 **Provide advice** on the proposed restrictions for expanded access to SGLT2 inhibitors recommended by the PBAC in March 2022, which have been updated to reflect the restriction changes to T2DM medicines implemented on 1 June 2024.
- 1.3 **Consider** the expanded PBS listings for SGLT2 inhibitors (dapagliflozin and empagliflozin, including combinations with metformin) for patients with T2DM and established CVD or high CV risk for suitability for inclusion in the increased maximum dispensed quantity (MDQ) measure.

## 2 Background

- 2.1 In September 2019, a stakeholder wrote to the PBAC requesting broader listings for glucagon-like peptide-1 receptor antagonists (GLP-1 RAs) and SGLT2 inhibitors on the PBS. The stakeholder considered that PBS reimbursement should support the use of these medicines in people with T2DM with CVD, or with multiple CV risk factors, and HbA1c >6.5%, based on the results of several CV outcome trials.

### **Registration status**

- 2.2 Dapagliflozin (Forxiga®) was TGA registered on 22 October 2012 and is indicated for glycaemic control in adults with T2DM:
- as monotherapy as an adjunct to diet and exercise in patients for whom metformin is otherwise indicated but was not tolerated
  - as initial combination therapy with metformin, as an adjunct to diet and exercise, to improve glycaemic control when diet and exercise have failed to provide adequate glycaemic control and there are poor prospects for response to metformin monotherapy (for example, high initial HbA1c levels)
  - in combination with other anti-hyperglycaemic agents to improve glycaemic control, when these together with diet and exercise, do not provide adequate glycaemic control.
- 2.3 Dapagliflozin is also TGA-indicated for prevention of hospitalisation for heart failure in adults with T2DM and established CVD or risk factors for CVD, and for the treatment of heart failure and chronic kidney disease (CKD).
- 2.4 Empagliflozin (Jardiance®) was TGA registered on 30 April 2014 and is indicated for glycaemic control in adults with T2DM as:
- Monotherapy: When diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance.
  - Add-on combination therapy: In combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.
- 2.5 Empagliflozin is also TGA-indicated for the prevention of CV death in patients with T2DM and established CVD, and for the treatment of heart failure and CKD.

### **Current PBS listings**

- 2.6 At 1 June 2024, dapagliflozin and empagliflozin were listed on the PBS as Authority Required (STREAMLINED) listings for the treatment of T2DM, in patients with a HbA1c >7% despite treatment with at least one of: metformin, a sulfonylurea (SU), or insulin. The restrictions also require use in combination with at least one of: metformin, a SU, or insulin.
- 2.7 Dapagliflozin and empagliflozin are also PBS-listed for the treatment of chronic heart failure (CHF) and chronic kidney disease (CKD).
- 2.8 SGLT2 inhibitors are not PBS-subsided for use in combination with a GLP-1 RA, except where the SGLT2 inhibitor is prescribed for an indication other than T2DM, and the patient did not achieve a clinically meaningful glycaemic response to the SGLT2 inhibitor.

### **Cost-effectiveness review of SGLT2 inhibitors**

- 2.9 In 2019, the Department contracted the University of Melbourne to prepare a report on the cost-effectiveness of SGLT2 inhibitors versus SUs as add-on therapy to metformin without a glycaemic requirement, using the UK Prospective Diabetes Study Outcomes Model Version 2 (UKPDS OM2) modified to the Australian setting. The report concluded that:
- SGLT2 inhibitors decreased the risk of all-cause and CV-related mortality when compared to SUs. In addition, reductions in systolic blood pressure and weight, but not HbA1c, were seen when comparing SGLT2 inhibitors to SUs in the treatment of T2DM.
  - SGLT2 inhibitors were likely to improve life expectancy and quality adjusted life expectancy (quality-adjusted life years, or QALYs) versus SUs, but were likely to lead to an overall increase in lifetime healthcare costs per patient.
- 2.10 The cost-effectiveness review (CER) forecasts incremental cost-effectiveness ratios (ICERs) of \$29,939 per QALY gained for men and \$27,316 per QALY gained for women, based on a lifetime treatment effect duration. These ICERs apply to the Australians with T2DM who are treated with SGLT2 inhibitors as dual therapy with metformin, i.e., the populations eligible for SGLT2 inhibitors under the current T2DM listings and the proposed population.

### **PBAC Consideration**

#### **November 2021**

- 2.11 In November 2021, the PBAC considered the cost-effectiveness report for SGLT2 inhibitors, along with proposed restriction changes. The PBAC deferred a decision to recommend expanding the listings of SGLT2 inhibitors to allow subsidised access for T2DM patients with established CVD or high CV risk, as add-on therapy to metformin, without the requirement to have a specific unmet glycaemic target. The PBAC had several concerns, including:
- the net cost to the R/PBS over the first five years of listing was very high and uncertain
  - the cost-effectiveness of the proposed listings was uncertain given the ICER for the base case and sensitivity analyses were higher than the PBAC would normally accept for preventative treatments
  - effectively targeting the eligible population in the proposed PBS restrictions, specifically patients with T2DM with high CV risk.
- 2.12 The PBAC noted the DUSC advice (October 2021) regarding the significant uncertainty in estimating the eligible population that will access SGLT2 inhibitors. The PBAC considered that a price reduction for SGLT2 inhibitor medicines would be required to bring the ICER for the expanded listing into an acceptable range and to reduce the

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uncertainty in the overall budget impact. The PBAC requested that the Department provide revised modelled estimates.

### March 2022

- 2.13 In March 2022, the PBAC considered an Addendum to the cost-effectiveness report for SGLT2 inhibitors, which provided modelled ICERs and budget impact estimates assuming 15%, 25% and 50% price reductions to SGLT2 inhibitors for both the current T2DM and proposed CV risk market.
- 2.14 The PBAC recommended that SGLT2 inhibitors (dapagliflozin and empagliflozin) be listed as add-on therapy to metformin for the treatment of T2DM patients with CVD, or high CV risk, if expenditure over the five years (2022-2026) for the current T2DM market and the proposed CVD/high CV risk population was limited to \$1.5 billion. The PBAC noted that based on the estimates in the Addendum this would equate to a price reduction for SGLT2 inhibitors in the order of 15% for T2DM indications.
- 2.15 The PBAC requested a utilisation analysis of T2DM medicines focussing on use of GLP-1 RAs, SGLT2 inhibitors and DPP4 inhibitors outside the PBS restrictions.

### November 2022

- 2.16 In November 2022, PBAC considered the DUSC analysis on '*Medicines for the treatment of type 2 diabetes – September 2022*'. The PBAC noted that in 2021, around 15% of people supplied an SGLT2 inhibitor received this medicine without concomitant use of metformin, a SU, or insulin; and around 14% of people supplied an SGLT2 inhibitor received this medicine in combination with a GLP-1 RA. The PBAC recommended a price reduction of at least 15% in the cost of SGLT2 inhibitors to account for the proportion of use outside the restrictions for which cost-effectiveness had not been considered.

### March 2023

- 2.17 In March 2023, the PBAC recommended that if the November 2022 recommendation for a 15% price reduction to SGLT2 inhibitors to account for use outside of the PBS restrictions was implemented, then the listings for dapagliflozin and empagliflozin could be expanded in line with the March 2022 recommendation (i.e., to include the CV risk population) without a further price reduction or a financial cap.

### December 2023

- 2.18 In December 2023, the PBAC considered recent research on the effectiveness and safety of GLP-1 RAs, and combination use of GLP-1 RAs with SGLT2 inhibitors. The PBAC noted that its March 2022 recommendation to list SGLT2 inhibitors for use in patients with T2DM and CVD or high CV risk had not progressed. The PBAC requested that the Department provide updated financial estimates for this proposed listing.

### March 2024

- 2.19 In March 2024, the PBAC recommended the PBS listing of dapagliflozin with sitagliptin FDC, Sidapvia®. The PBAC recommended that the cost-effectiveness would be

acceptable if it were cost-minimised to the lowest cost PBS-listed SGLT2 inhibitor + DPP4 inhibitor FDC.

### ***Stakeholder correspondence/engagement***

- 2.20 Sponsors of PBS-listed SGLT2 inhibitors were consulted on the SGLT2 inhibitor cost-effectiveness report prior to the October 2021 DUSC and ESC meetings, and the November 2021 and March 2022 PBAC meetings.
- 2.21 Sponsors were provided an opportunity to provide a pre-PBAC response to this item in line with standard PBAC timelines.

## **3 Current Status**

### ***Revised estimated PBS usage and financial implications***

- 3.1 The Department provided revised estimates of the PBS usage and budget impact for the recommended expansion of the PBS listings for SGLT2 inhibitors to include patients with T2DM and established CVD or high CV risk.
- 3.2 The net cost for the expanded SGLT2 inhibitor listings, in combination with a 15% price reduction to the current and expanded SGLT2 inhibitor listings, was estimated to be \$4.8 million in 2024, increasing to \$11.5 million in 2029 (total of \$49.0 million over 2024-2029) (Table 2).

**Table 2: Net cost to R/PBS for expanded SGLT2 inhibitor listing, incorporating 15% price reduction to the current and expanded T2DM market – base case**

<b>Year</b>	<b>Net R/PBS cost</b>
2024	\$4,787,464
2025	\$5,530,583
2026	\$6,905,462
2027	\$8,780,590
2028	\$11,504,585
2029	\$11,489,748
<b>Total</b>	<b>\$48,998,432</b>

- 3.3 For comparison, the March 2022 estimated budget impact was \$85.2 million in 2024, increasing to \$157.6 million in 2028 (total of \$605.8 million over 2024-2028). These estimates were based on a linear projection of the patient population currently on regimens containing only metformin, or metformin plus a SU. The estimates assumed an uptake rate of 50% in the first year of listing, increasing by 10% per annum to a rate of 90%. Both the DUSC and the PBAC noted the high uncertainty in the estimated population and financial estimates.

3.4 The March 2022 financial estimates did not consider several important factors that may limit the size of the population eligible to access SGLT2 inhibitor therapy under the expanded restrictions:

- the proportion of patients with CVD or high CV risk
- the current HbA1c of T2DM patients in Australia on metformin monotherapy
- the progressive nature of T2DM which means that HbA1c tends to increase over time in the absence of therapy changes
- clinical inertia and the appropriateness of treating patients with HbA1c <7%.

**Eligible patient population – Patients on metformin + SU therapy**

3.5 Under the current SGLT2 inhibitor restrictions, patients are eligible for SGLT2 inhibitor therapy if they are using metformin and have a HbA1c >7%. The revised estimates removed the patient population on regimens containing metformin plus a SU on the assumption that most of these patients are likely to have had a HbA1c >7% on metformin monotherapy prior to adding a SU and therefore, would already have been eligible for SGLT2 inhibitor therapy. This assumption was based on the increased risk of hypoglycaemia associated with SUs and studies reporting increased mortality risk (likely associated with increased risk of hypoglycaemia) to patients from intensive glycaemic control (e.g., HbA1c <6.5%).

3.6 A sensitivity analysis was undertaken that included the projected patient population on metformin plus SU dual therapy (results are shown in Table 3).

**Eligible patient population – Change from linear to trendline patient projection**

3.7 The March 2022 financial estimates used a linear projection of the patient population currently on regimens containing only metformin, or metformin plus a SU, to estimate the eligible CV risk population, and a linear projection of patients using SGLT2 inhibitors was used to project the current T2DM market (i.e., the offset population). The updated financial model used a logarithmic trendline projection based on DUSC data for prescriptions supplied between 2018 and 2023 for projecting patients using only metformin, and from 2015 to 2023 to project patients using SGLT2 inhibitors for T2DM indications. The projected number of patients on metformin only regimens in 2024 was adjusted to be the average between the number of patients in 2023 and 2025, due to the trendline projecting lower patient numbers in 2024 than 2023.

**Eligible patient population – Estimation of proportion of patients with CVD/high CV risk**

3.8 The March 2022 financial estimates did not consider the proportion of patients on metformin monotherapy that were likely to have CVD or be at high CV risk. For the revised estimates, DUSC data based on PBS prescriptions supplied in 2023 was used to estimate the proportion of patients on regimens containing only metformin, or metformin + SU, who were also taking CV medication/s. Based on this data, 74.17% of patients on metformin monotherapy were assumed to have CVD or be at high CV risk.

### Eligible patient population – Estimation of proportion of patients with HbA1c >7%

3.9 Population studies indicate that many patients on T2DM monotherapy in Australia are likely to have a HbA1c >7% and would be eligible for SGLT2 inhibitor therapy under the current restrictions. The revised budget impact assumed that 50% of T2DM patients on metformin monotherapy are likely to have a HbA1c >7%. This estimate was based on the following studies:

- The Australian National Diabetes Audit – Australian Quality Clinical Audit 2021, which found that among adult patients with diabetes (N=4,262), median HbA1c was 62.0 mmol/mol (7.8%) for patients with T2DM.<sup>1</sup>
- An analysis of NPS MedicineInsight data of Australian general practice patients, which found that in 2020-21, of patients with a diagnosis of diabetes that had their HbA1c level checked during the year (N=115,475), around 55% had at least one HbA1c test result >7%.<sup>2</sup>
- An analysis of NPS MedicineInsight data of Australian general practice patients with T2DM and a HbA1c test result recorded between 2013-2015 (N~70,000), which found that these patients had a mean HbA1c of 7.1% (Standard deviation [SD] 1.4%), however only 40.8% of patients had a HbA1c >7%. Around 28% of patients were using no diabetes medication, 34% were on one diabetes medication, 19% were on two diabetes medications, 5% were on three or more medications, and 15% were on insulin without or without other medications.<sup>3</sup>
- A study of over 6,400 patients, collected from around 250 Australian general practices in Victoria, which indicated that for T2DM patients on oral glucose-lowering agents, the mean HbA1c was >7%. Patients with ischaemic heart disease and CKD were excluded from this study.<sup>4</sup>
- The Australian Health Survey 2011–12, which found that around 44% of people aged 18 years and over with known diabetes (N~400) had an HbA1c test result of >7%.<sup>5</sup>
- A UKPDS study of patients newly diagnosed with diabetes which found that after 3 years around 50% of T2DM patients on monotherapy had a HbA1c of >7%.<sup>6</sup>

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<sup>1</sup> Australian Institute of Health and Welfare, [Diabetes: Australian facts](#), accessed 21 February 2024.

<sup>2</sup> NPS MedicineWise, '[General Practice Insights Report July 2020-June 2021](#)', Sydney: NPS MedicineWise, 2022.

<sup>3</sup> Chiang JI et al. (2020), '[Associations between multimorbidity and glycaemia \(HbA1c\) in people with type 2 diabetes: cross-sectional study in Australian general practice](#)', *BMJ Open*, 10(11): e039625.

<sup>4</sup> Imai, C et al (2021), '[Adherence to guideline-recommended HbA1c testing frequency and better outcomes in patients with type 2 diabetes: a 5-year retrospective cohort study in Australian general practice](#)', *BMJ Quality & Safety*, 30(9):706-714.

<sup>5</sup> Australian Bureau of Statistics, [Australian Health Survey: Biomedical results for Chronic Diseases – Diabetes \(2011-12\)](#), accessed 23 February 2024.

<sup>6</sup> Turner RC, et al. (1999) 'Glycaemic control with diet, sulfonylurea, metformin, or insulin in patients with type 2 diabetes mellitus – Progressive requirement for multiple therapies (UKPDS 49)',

- An analysis of the US National Health and Nutrition Examination Survey database from 2007-2010, which found that only 52.5% of people with diabetes achieved an HbA1c of <7%.<sup>7</sup>

3.10 A sensitivity analysis was undertaken to reduce the estimate of the proportion of patients on metformin monotherapy with HbA1c >7% to 40% (results are shown in Table 3).

**Eligible patient population – Estimation of proportion of patients progressing to HbA1c >7%**

3.11 The March 2022 estimates did not consider the progressive nature of T2DM. Patients on metformin monotherapy with a HbA1c of ≤7% may, over the course of the forward estimates, progress to having a HbA1c >7% and therefore be eligible for SGLT2 inhibitor therapy under the current PBS restrictions. The revised budget estimates assumed that 15% per annum of T2DM patients on metformin monotherapy with an HbA1c ≤7% would progress to having a HbA1c >7%.

3.12 The 15% estimate was based on the following studies of the progression of untreated patients with impaired fasting glucose (IFG) and/or impaired glucose tolerance (IGT) ('prediabetes') to diabetes:

- A systematic review and meta-analysis of prospective studies published between 1979-2004, which estimated the annual incidence of progression to T2DM in subjects with IFG and IGT at 12.13% (95% CI: 4.27-20.00), and at around 5-7% for subjects with IGT or IFG.<sup>8</sup>
- A meta-analysis of prospective observational studies in which participants had prediabetes at baseline (defined as HbA1c 6.0-6.4%), which found an incidence rate for progression to diabetes of 35.6 (95% credible interval: 15.1 to 83.0) per 1000 person-years.<sup>9</sup>
- A US study which found a 5.5% per annum conversion rate for patients with IFG (110-125 mg/dL) to T2DM. CV risk factors such as high BMI, blood pressure and triglycerides, and lower HDL cholesterol, were associated with faster diabetes development.<sup>10</sup>

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<sup>7</sup> Pantalone KM et al (2016) 'Intensification of diabetes therapy and time until A1c goal attainment among patients with newly diagnosed type 2 diabetes who fail metformin monotherapy within a large integrated health system', *Diabetes Care*, 39(9): 1527-1534.

<sup>8</sup> Gerstein HC (2007) 'Annual incidence and relative risk of diabetes in people with various categories of dysglycaemia: a systematic review and meta-analysis of prospective studies'

<sup>9</sup> Morris DH et al (2013) 'Progression rates from HbA1c 6.0-6.4% and other prediabetes definitions to type 2 diabetes: a meta-analysis', *Diabetologica*, 56(7):1489-93.

<sup>10</sup> Nichols GA et al. (2007) 'Progression from newly acquired impaired fasting glucose to type 2 diabetes', *Diabetes Care*, 30(2):228-233.



- A prospective cohort study of a Dutch population which found that around 65% of participants with both IFG and impaired post-load glucose levels progressed to diabetes during the 6-year follow-up.<sup>11</sup>
- 3.13 The definition of ‘prediabetes’ has changed over time and the rate of HbA1c progression in people with ‘prediabetes’ may not be the same as the rate of progression in those with diabetes. As noted in some studies, patients with CV risk factors may have faster HbA1c progression.
- 3.14 Placebo-controlled RCTs examining add-on therapies to metformin cannot be used to inform an understanding of the rate of HbA1c progression in T2DM patients, as due to placebo effect, these trials often show a reduction in HbA1c in the placebo arm. However, a randomised trial of metformin versus placebo in subjects with elevated fasting and post-load plasma glucose, found an incidence of diabetes development in the placebo arm of 11.0 cases per 100 person-years.<sup>12</sup>
- 3.15 A sensitivity analysis was undertaken to reduce the annual rate by which T2DM patients on metformin monotherapy with HbA1c  $\leq 7\%$  convert to a HbA1c  $>7\%$  to  $10\%$  (refer Table 3).

#### Uptake rate

- 3.16 The financial estimates used a revised uptake rate, or percentage of patients electing treatment, of 50% in 2024, increasing by 5% per annum to a maximum of 70%. The March 2022 estimates used an uptake rate of 50% in 2024, increasing by 10% per annum to a maximum of 90%. A sensitivity analysis providing a flat 50% uptake rate was provided (Table 3).
- 3.17 Clinical guidelines generally recommend that HbA1c targets vary according to patient characteristics. HbA1c targets for patients who are older ( $\geq 65$  years) with comorbidities/poor health or long duration of diabetes would often be over 7% to reduce the risk of adverse events, particularly hypoglycaemia.<sup>13</sup> The guideline published by the Royal Australian College of General Practitioners (RACGP) recommends a general HbA1c target of  $\leq 7\%$ , but notes that less stringent targets may be appropriate for those at risk from hypoglycaemia, of reduced life expectancy or longer diabetes duration, or in those with comorbidities or established vascular complications. The guideline states, “Glycaemic targets for some elderly people may be higher than for the non-elderly (e.g., a glycated haemoglobin [HbA1c] target of 8% [64 mmol/mol], rather than 7% [53 mmol/mol]). Intensive glycaemic management reduces microvascular but not macrovascular complications and may increase adverse

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<sup>11</sup> De Vegt F, Dekker JM and Jager A (2001) ‘Relation of impaired fasting and postload glucose with incident type 2 diabetes in a Dutch population: The Hoorn Study’ *JAMA*, 285(16):2109-13.

<sup>12</sup> Diabetes Prevention Program Research Group (2002), ‘[Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin](#)’, *New England Journal of Medicine*, 346:393-403.

<sup>13</sup> American Diabetes Association (2024) ‘13. Older Adults: Standards of care in diabetes - 2024’, *Diabetes Care*, 47(Supplement 1):S244-257.

events and mortality.”<sup>14</sup> Elderly patients with longer duration of diabetes may also be less likely to gain macrovascular benefits from intensive glycaemic control.<sup>15</sup>

- 3.18 The ACCORD trial showed increased all-cause mortality in the intensive control group (HbA1c 6.4%) and patients experiencing severe hypoglycaemia were noted to have increased mortality rates. However, the ACCORD study did not include SGLT2 inhibitors, and these medications are associated with minimal hypoglycaemia risk. A review of the benefits and harms of intensive glycaemic control concluded that moderate HbA1c targets of 7-8% are adequate for most patients with T2DM, as the evidence from systematic reviews and meta-analyses suggested no demonstrable benefits on macrovascular or microvascular outcomes of intensive (HbA1c <7%) glycaemic control, with the exception of a reduction in the relative risk of non-fatal myocardial infarction, but was associated with a 2-3 fold increased risk of severe hypoglycaemia.<sup>16</sup>
- 3.19 An American College of Physicians guideline released in April 2024 recommends ‘Clinicians should aim to achieve HbA1c levels between 7% and 8% in most adults with type 2 diabetes and deintensify treatments in adults with Hba1c levels less than 6.5%’.<sup>17</sup> Under these guidelines, most patients would be considered inappropriate for add-on SGLT2 inhibitor therapy until their HbA1c was >7% (i.e., under the PBS restrictions, the currently eligible patient population).
- 3.20 Therapeutic inertia in T2DM management is considered high. A systematic review found that most included studies showed clinical inertia rates of over 50% of T2DM patients (USA: 35.4% to 85.8% [mean: 60.6%]; UK: 22.1% to 69.1% [mean: 45.6%]; France: 31.0% to 42.3% [mean: 36.6%]; Spain: 18.1% to 60.0% [mean 39.0%]; Canada: 65.8%; Germany and Austria: 55.6%).<sup>18</sup> The review identified 25 studies, mostly retrospective cohort studies, including >575, 000 patients. The definition of clinical inertia varied between studies and included lack of individualisation of treatment goals; and failure to initiate or intensify treatment based on evidence-based guidelines, or when HbA1c levels were above target. Baseline treatments also varied between studies. One study, an analysis of US health records for around 28,000 patients with T2DM and HbA1c ≥8.0% showed that no new class of glucose-lowering therapy had been added at 6 months for 36% of patients on one glucose-lowering therapy. Studies indicate that therapeutic inertia is higher for patients close to HbA1c

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<sup>14</sup> The Royal Australian College of General Practitioners (2020) ‘[Management of type 2 diabetes. A handbook for general practice](#)’. East Melbourne, Victoria: RACGP. March 2021 update.

<sup>15</sup> Westall SL et al. (2022) ‘[The individualisation of glycaemic targets in response to patient characteristics in type 2 diabetes: a scoping review](#)’, *Clinical Medicine*, 22(3): 257-65.

<sup>16</sup> Rodriguez-Gutierrez R et al (2019) ‘[Benefits and harms of intensive glycaemic control in patients with type 2 diabetes](#)’, 367:15887.

<sup>17</sup> Qaseem A et al. (2024) ‘[Newer Pharmacologic Treatments in Adults with Type 2 Diabetes: A clinical Guidelines From the American College of Physicians](#)’, *Annals of Internal Medicine*, 177(5): 658-68.

<sup>18</sup> Almigbal TH et al. (2023) ‘Clinical inertia in the management of type 2 diabetes mellitus: A systematic review’, *Medicina*, 59(1):182.

targets (i.e., 7-8%) and those at earlier stages of diabetes management, e.g., monotherapy.<sup>19</sup>

- 3.21 Therefore, many patients who would meet the eligibility criteria for earlier subsidised access to SGLT2 inhibitors may not be prescribed these medicines due to either therapeutic inertia, or because the clinician deems it inappropriate to add an SGLT2 inhibitor to the patient's regimen due to the risk of adverse events or reduced clinical benefit. Cost and patient preference would also contribute to a clinician's decision to prescribe an SGLT2 inhibitor and influence whether the patient fills the prescription. Many patients with a HbA1c below 7% and low to moderate glycaemic variability would experience minimal hyperglycaemia symptoms and may consider their diabetes to be well-managed. They may therefore be unwilling to use additional medication. Initial medication non-adherence (not obtaining a medication the first time it is prescribed) has shown rates between 6-28% in primary care, with predictive factors including taking more than 3 medications, being female and younger age.<sup>20</sup>
- 3.22 The base case in the revised financial model used an uptake rate of 50% in 2024, increasing by 5% per annum to a maximum of 70%, to represent an increase over time in clinician and consumer awareness of the CV benefits of SGLT2 inhibitors which may be independent of their glycaemic effects. A sensitivity analysis was undertaken to change the uptake rate to a constant rate of 50% (Table 3), based on the review of clinical inertia rates in diabetes.

#### **Additional considerations/assumptions**

- 3.23 The revised financial estimates did not specifically consider the proportion of patients who are contraindicated or intolerant to SGLT2 inhibitors, which may lead to an overestimation of cost to the PBS. The estimates also did not consider the proportion of patients contraindicated or intolerant to metformin, which may lead to an underestimation of the cost to the PBS. The recommended SGLT2 inhibitor restriction changes for the expanded CV risk population from March 2022, allow patients contraindicated or intolerant to metformin to access SGLT2 inhibitor monotherapy. Therefore, some patients currently using first-line medications other than metformin, such as sulfonylureas or pioglitazone, may switch to an SGLT2 inhibitor. Other potential switches, such as from insulin or DPP4 inhibitors, are unlikely to be significantly more costly to the PBS than an SGLT2 inhibitor, and the DUSC utilisation analysis of T2DM medicines indicated that patients were likely already using SGLT2 inhibitors in monotherapy.
- 3.24 The updated financial estimates assumed that eligible patients add either dapagliflozin or empagliflozin single component products, rather than moving to an

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<sup>19</sup> Rattleman CR et al. (2021) '[A retrospective analysis of therapeutic inertia in type 2 diabetes management across diverse population of health care organizations in the USA](#)', *Diabetes Therapy*, 12(2):581-94.

<sup>20</sup> Aznar-Lou, I. (2017) 'Initial medication non-adherence: prevalence and predictive factors in a cohort of 1.6 million primary care patients', *Br J Clinical Pharmacol*, 83(6):1328-40.

FDC with metformin. Modelling a proportion of patients moving to an FDC may or may not reduce the cost estimates to the R/PBS, as FDCs generally cost less than the component medicines, but there would be reduced patient co-payments.

- 3.25 The recommended restriction changes allow access to SGLT2 inhibitors for patients who identify as Aboriginal and Torres Strait Islander and are on metformin therapy. This population was not specifically modelled, as it was considered likely to be predominantly included within the estimates of the eligible population, as patients on metformin therapy and CV medications. However, this assumption may have led to an underestimation of the eligible population.
- 3.26 The financial estimates do not take into consideration the impacts of 60-day prescription items.

### **Sensitivity analyses**

- 3.27 The results of the sensitivity analyses detailed above are shown in Table 3. The model was sensitive to changes in the estimate of the proportion of patients on metformin monotherapy with HbA1c >7%. Reducing this from 50% in the base case to 40% in the sensitivity analysis doubled the estimated R/PBS expenditure over 2024-2029 to \$100.0 million (+104%; sensitivity analysis 2). Including patients on regimens of metformin + SU therapy in the model had a moderate impact on the cost estimates (+28%; sensitivity analysis 1), as did changing the annual rate at which patients on metformin monotherapy convert to HbA1c >7% from 15% to 10% (+31%; sensitivity analysis 3). Changing the uptake rate to a constant rate of 50% resulted in the expanded listing being almost cost neutral (\$0.5 million over the forward estimates; -99%; sensitivity analysis 4).

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**Table 3: Sensitivity analyses of net cost to R/PBS for expanded SGLT2 inhibitor listing, incorporating 15% price reduction to the current and expanded T2DM market**

Assumption/Variable	Net R/PBS cost (2024-2029)	% impact versus base case
Base case	\$48,998,432	NA
1. Projected patient population current therapy - Include patients on met + SU therapy (Base case: met only)	\$62,516,694	28%
2. Proportion of patients with T2DM on met monotherapy with HbA1c >7% - Reduce to 40% (Base case: 50%)	\$99,888,251	104%
3. Annual rate T2DM patients on met monotherapy with HbA1c 6.5% to ≤7% convert to HbA1c >7% - Reduce to 10% (Base case: 15%)	\$63,966,035	31%
4. Uptake rate - Change to 50% (Base case: 50% in 2024 increasing by 5% per year to 70%)	\$499,403	-99%
1, 2 and 3 ('Worst case scenario')	\$135,025,519	176%
1,2,3 and 4	\$70,290,810	43%

**60-day prescriptions**

3.28 On 1 March 2024, under Stage Two of 60-day prescriptions, the following increased MDQ SGLT2 inhibitor PBS items were implemented:

- dapagliflozin, dapagliflozin + metformin, saxagliptin + dapagliflozin (continuing treatment for T2DM)
- dapagliflozin for CHF (left ventricular ejection fraction of less than or equal to 40%)
- empagliflozin, empagliflozin + linagliptin and empagliflozin + metformin (continuing treatment for T2DM)
- empagliflozin for CHF (left ventricular ejection fraction of less than or equal to 40%).

3.29 Dapagliflozin and empagliflozin were not PBS-listed for CKD at the time of PBAC's consideration of increased MDQ at its December 2022 meeting.

3.30 In March 2024, the PBAC recommended the PBS listing of dapagliflozin + sitagliptin and considered that it would be reasonable to include this FDC in the 60-day prescription measure.

3.31 The PBAC was requested to consider the suitability of the expanded PBS listings for SGLT2 inhibitors (dapagliflozin and empagliflozin, including combinations with metformin) for patients with T2DM and established CVD or high CV risk for inclusion in the increased MDQ measure.

3.32 The PBAC December 2022 accepted guidance criteria for exclusion of a medicine/medicine group from the increased MDQ measure are shown in Table 4.

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**Table 4: Updated guidance for medicine/medicine group exclusion from the increased maximum dispensed quantity for chronic conditions proposal**

Criterion	Description
<b>A</b>	Medicines where being able to stockpile large quantities could pose a risk to patient safety (for example: narcotics, paracetamol/codeine, psychostimulants, psycholeptics and psychoanaleptics);
<b>B</b>	Medicines with a requirement for regular monitoring and frequent dose titration
<b>C</b>	Medicines where the drug regimen is associated with management of progressively worsening disease or the symptoms are associated with relapse of disease and the patient is not expected to be stable for the next twelve months
<b>D</b>	Medicines prescribed for short term management of symptoms in chronic diseases
<b>E</b>	Medicines in the Palliative Care section of the Schedule
<b>F</b>	Medicines where the PBAC has recommended a listing that enables prescribers to prescribe less than six months therapy per prescription
<b>G</b>	Medicines must be PBS listed for 5 or more years, or generics of medicines which have been listed for 5 or more years, as severe but rare adverse effects frequently become evident during this period.

3.33 In December 2022, the PBAC recommended the following updated PBS restriction criterion to differentiate the PBS items with increased MDQs from the current one-month supply items, shown in Table 5.

**Table 5: Restriction criterion for increased maximum dispensed quantity PBS items**

<b>Clinical criteria:</b>	The <i>condition</i> must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient
<b>Administrative Advice*</b>	No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised.

\*for inclusion only where this advice is currently included in the PBS restriction for the equivalent one-month PBS item

### **Updated SGLT2 inhibitor restriction changes**

3.34 In March 2023, July 2023, and March 2024, the PBAC recommended several changes to simplify and clarify the PBS restrictions for T2DM medicines including SGLT2 inhibitors, and address issues associated with use outside the restrictions. These changes were implemented on 1 June 2024.

3.35 The March 2022 recommended restriction changes to expand access to SGLT2 inhibitors for the CV risk population were updated to reflect the 1 June 2024 restriction changes. The PBAC was requested to consider removal of the following text from the Administrative Advice, *'The National Vascular Disease Prevention Alliance Guidelines for the management of Absolute Cardiovascular Disease Risk 2012 specify a range of conditions known to be at clinically determined high risk of CVD'*, as these guidelines have been updated.

### **Sponsor comments**

3.36 The PBAC noted two errors in the cost model workbook correctly identified in sponsor pre-PBAC responses. These included incorrect script numbers entered for dapagliflozin 5 mg with metformin 1000 mg, and not entering a co-payment group for one combination. The financial estimates in Tables 2 and 3 have been updated to correct these errors.

3.37 There was no hearing for this item.

### **Consumer comments**

3.38 The PBAC noted that no consumer comments were received for this item.

## **4 PBAC Outcome**

- 4.1 The PBAC confirmed its recommendation from March 2022 that the PBS listings for SGLT2 inhibitors be expanded to include add-on therapy to metformin for patients with T2DM and established CVD or high CV risk, without the requirement to have a specific unmet glycaemic target. The PBAC was satisfied that SGLT2 inhibitors provide, for some patients, a significant improvement in efficacy over sulfonylureas.
- 4.2 The PBAC confirmed its March 2023 recommendation that expansion of the SGLT2 inhibitor restrictions in line with the March 2022 recommendation would be acceptably cost-effective if the 15% price reduction to SGLT2 inhibitors for T2DM indications to account for use outside of the PBS restrictions was implemented, without the requirement for further price reductions or a financial cap.
- 4.3 The PBAC noted the revised inputs and assumptions used to estimate the PBS usage and financial implications for the expanded SGLT2 inhibitor listings and did not specify any changes to the base case model. The PBAC noted that the net cost for the expanded SGLT2 inhibitor listings, in combination with a 15% price reduction to the current and expanded SGLT2 inhibitor listings, was estimated to be \$49.0 million over 2024-2029. The PBAC considered that overall, while still uncertain, the revised cost estimates were reasonable.
- 4.4 The PBAC noted the evidence provided on clinical inertia rates in the treatment of T2DM and considered that uptake of the expanded SGLT2 inhibitor listings was likely to be significantly lower than the eligible population.
- 4.5 The PBAC considered that there were also high rates of undertreatment of kidney disease in Australia and that expansion of the SGLT2 inhibitor listings for T2DM patients may have additional benefits in reducing the progression of kidney disease in this population.
- 4.6 Regarding the proposed restriction, the PBAC considered it was appropriate to remove the reference to the 'Guidelines for the Management of Absolute Cardiovascular Disease Risk 2012' from the Administrative Advice and noted that there was a risk in including references to specific guidelines in PBS restrictions that these would become outdated over time. However, the PBAC considered that inclusion of the following definition of high CV risk in Administrative Advice may encourage good clinical practice and the use of a CV risk calculator: '*High cardiovascular risk is defined as an estimated risk of a cardiovascular event of  $\geq 10\%$  over 5 years*'. The PBAC noted that this was the

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current definition of high CV risk in the 'Australian Guidelines for assessing and managing cardiovascular disease risk 2023'.<sup>21</sup>

- 4.7 The PBAC recommended that the expanded SGLT2 inhibitor listings were suitable for inclusion in the increased MDQ measure. The financial estimates did not include the increased MDQ listings and the PBAC noted that the Department would revise the financial estimates to account for this.

**Outcome:**

Recommended

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<sup>21</sup> Commonwealth of Australia as represented by the Department of Health and Aged Care. (2023) [Australian Guidelines for assessing and managing cardiovascular disease risk](#).



## 5 Recommended listing

### 5.1 Amend existing listings as follows:

#### **SGLT2 inhibitor**

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
DAPAGLIFLOZIN dapagliflozin 10 mg tablet, 28	10011X MP NP	1	28	5	Forxiga
EMPAGLIFLOZIN empagliflozin 10 mg tablet, 30	10206E MP NP	1	30	5	Jardiance
EMPAGLIFLOZIN empagliflozin 25 mg tablet, 30	10202Y MP NP	1	30	5	Jardiance

#### **Restriction Summary New / Treatment of Concept: New**

<b>Concept ID</b>	<b>Category / Program:</b> GENERAL – General Schedule (Code GE)
(for internal Dept. use)	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
	<b>Restriction Type</b> <input checked="" type="checkbox"/> Authority Required – Streamlined [new code]
	<b>Condition:</b> Diabetes mellitus type 2
8995	<b>Indication:</b> Diabetes mellitus type 2
New CC1	<b>Clinical criteria:</b>
New CC1.1	The treatment must be in combination with metformin; unless contraindicated/intolerant.
	<b>AND</b>
New CC2	<b>Clinical criteria:</b>
CC2.1	Patient must have cardiovascular disease; or
CC2.2	Patient must be at high risk of a cardiovascular event; or
CC2.3	Patient must identify as Aboriginal or Torres Strait Islander.
New TC1	<b>Treatment criteria:</b>
TC1.1	The patient must not be undergoing concomitant PBS-subsidised treatment for this condition with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.
New AA1	<b>Administrative Advice</b> The Australian Absolute Cardiovascular Disease Risk Calculator is available at <a href="http://www.cvdcheck.org.au">www.cvdcheck.org.au</a> . High cardiovascular risk is defined as an estimated risk of a cardiovascular event of $\geq 10\%$ over 5 years.
7703	<b>Continuing Therapy Only:</b> For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.
New AA2	<b>Administrative Advice</b> Abbreviations used in the restriction are as follows: SGLT2 – sodium glucose cotransporter 2 inhibitor (drug names ending in 'flozin') DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin') GLP-1 – glucagon-like peptide-1 receptor agonist

**SGLT2 inhibitor combinations with metformin**

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
DAPAGLIFLOZIN + METFORMIN dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28	10515K MP NP	1	28	5	Xigduo XR 10/1000
DAPAGLIFLOZIN + METFORMIN dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56	10510E MP NP	1	56	5	Xigduo XR 5/1000
DAPAGLIFLOZIN + METFORMIN dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28	10516L MP NP	1	28	5	Xigduo XR 10/500
EMPAGLIFLOZIN + METFORMIN empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60	10677Y MP NP	1	60	5	Jardiamet 12.5 mg/1000 mg
EMPAGLIFLOZIN + METFORMIN empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60	10627H MP NP	1	60	5	Jardiamet 5 mg/1000 mg
EMPAGLIFLOZIN + METFORMIN empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60	10633P MP NP	1	60	5	Jardiamet 12.5 mg/500 mg
EMPAGLIFLOZIN + METFORMIN empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60	10626G MP NP	1	60	5	Jardiamet 5 mg/500 mg

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Restriction Summary New / Treatment of Concept: New

<b>Concept ID</b>	<b>Category / Program:</b> GENERAL – General Schedule (Code GE)
(for internal Dept. use)	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
	<b>Restriction Type</b> <input checked="" type="checkbox"/> Authority Required – Streamlined [new code]
	<b>Condition:</b> Diabetes mellitus type 2
8995	<b>Indication:</b> Diabetes mellitus type 2
<b>New CC1</b>	<b>Clinical criteria:</b>
CC1.1	Patient must have cardiovascular disease; or
CC1.2	Patient must be at high risk of a cardiovascular event; or
CC1.3	Patient must identify as Aboriginal or Torres Strait Islander.
<b>New TC1</b>	<b>Treatment criteria:</b>
TC1.1	The patient must not be undergoing concomitant PBS-subsidised treatment <u>for this condition</u> with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.
<b>New AA1</b>	<b>Administrative Advice</b> The Australian Absolute Cardiovascular Disease Risk Calculator is available at <a href="http://www.cvdcheck.org.au">www.cvdcheck.org.au</a> . High cardiovascular risk is defined as an estimated risk of a cardiovascular event of $\geq 10\%$ over 5 years.
7703	<b>Continuing Therapy Only:</b> For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.
<b>New AA2</b>	<b>Administrative Advice</b> Abbreviations used in the restriction are as follows: SGLT2 – sodium glucose cotransporter-2 inhibitor (drug names ending in ‘flozin’) DPP4 – dipeptidyl peptidase-4 inhibitor (drug names ending in ‘gliptin’) GLP-1 – glucagon-like peptide-1 receptor agonist

**MDQ listings – SGLT2 inhibitor**

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
DAPAGLIFLOZIN dapagliflozin 10 mg tablet, 28	13844P MP NP	2	56	5	Forxiga
EMPAGLIFLOZIN empagliflozin 10 mg tablet, 30	13845Q MP NP	2	60	5	Jardiance
EMPAGLIFLOZIN empagliflozin 25 mg tablet, 30	13920P MP NP	2	60	5	Jardiance

**Restriction Summary New / Treatment of Concept: New**

<b>Concept ID</b>	<b>Category / Program:</b> GENERAL – General Schedule (Code GE)
(for internal Dept. use)	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
	<b>Restriction Type</b> <input checked="" type="checkbox"/> Authority Required – Streamlined [new code]
	<b>Condition:</b> Diabetes mellitus type 2
8995	<b>Indication:</b> Diabetes mellitus type 2
30503	<b>Clinical criteria</b>
30502	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient,
	<b>AND</b>
New CC1	<b>Clinical criteria:</b>
New CC1.1	The treatment must be in combination with metformin; unless contraindicated/intolerant,
	<b>AND</b>
New CC2	<b>Clinical criteria:</b>
CC2.1	Patient must have cardiovascular disease; or
CC2.2	Patient must be at high risk of a cardiovascular event; or
CC2.3	Patient must identify as Aboriginal or Torres Strait Islander.
New TC1	<b>Treatment criteria:</b>
TC1.1	The patient must not be undergoing concomitant PBS-subsidised treatment <u>for this condition</u> with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.
New AA1	<b>Administrative Advice</b> The Australian Absolute Cardiovascular Disease Risk Calculator is available at <a href="http://www.cvdcheck.org.au">www.cvdcheck.org.au</a> . High cardiovascular risk is defined as an estimated risk of a cardiovascular event of ≥10% over 5 years.
7703	<b>Continuing Therapy Only:</b> For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.
New AA2	<b>Administrative Advice</b> Abbreviations used in the restriction are as follows: SGLT2 – sodium glucose cotransporter 2 inhibitor (drug names ending in 'flozin') DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin') GLP-1 – glucagon-like peptide-1 receptor agonist

**MDQ listings - SGLT2 inhibitor combinations with metformin**

Name, Restriction, Manner of administration and form	PBS item code	Max. qty packs	Max. qty units	№. of Rpts	Available brands
DAPAGLIFLOZIN + METFORMIN dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28	13875G MP NP	2	56	5	Xigduo XR 10/1000
DAPAGLIFLOZIN + METFORMIN dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56	13851B MP NP	2	112	5	Xigduo XR 5/1000
DAPAGLIFLOZIN + METFORMIN dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28	14028H MP NP	2	56	5	Xigduo XR 10/500
EMPAGLIFLOZIN + METFORMIN empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60	13987E MP NP	2	120	5	Jardiamet 12.5 mg/1000 mg
EMPAGLIFLOZIN + METFORMIN empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60	13852C MP NP	2	120	5	Jardiamet 5 mg/1000 mg
EMPAGLIFLOZIN + METFORMIN empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60	13903R MP NP	2	120	5	Jardiamet 12.5 mg/500 mg
EMPAGLIFLOZIN + METFORMIN empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60	14029J MP NP	2	120	5	Jardiamet 5 mg/500 mg

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Restriction Summary New / Treatment of Concept: New

Concept ID	<b>Category / Program:</b> GENERAL – General Schedule (Code GE)
(for internal Dept. use)	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
	<b>Restriction Type</b> <input checked="" type="checkbox"/> Authority Required – Streamlined [new code]
	<b>Condition:</b> Diabetes mellitus type 2
8995	<b>Indication:</b> Diabetes mellitus type 2
30503	<b>Clinical criteria</b>
30502	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient,
	<b>AND</b>
New CC1	<b>Clinical criteria:</b>
CC1.1	Patient must have cardiovascular disease; or
CC1.2	Patient must be at high risk of a cardiovascular event; or
CC1.3	Patient must identify as Aboriginal or Torres Strait Islander.
New TC1	<b>Treatment criteria:</b>
TC1.1	The patient must not be undergoing concomitant PBS-subsidised treatment <u>for this condition</u> with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.
New AA1	<b>Administrative Advice</b> The Australian Absolute Cardiovascular Disease Risk Calculator is available at <a href="http://www.cvdcheck.org.au">www.cvdcheck.org.au</a> . High cardiovascular risk is defined as an estimated risk of a cardiovascular event of $\geq 10\%$ over 5 years.
7703	<b>Continuing Therapy Only:</b> For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.
New AA2	<b>Administrative Advice</b> Abbreviations used in the restriction are as follows: SGLT2 – sodium glucose cotransporter-2 inhibitor (drug names ending in 'flozin') DPP4 – dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin') GLP-1 – glucagon-like peptide-1 receptor agonist

*These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.*

## 6 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.