

## 10.06 PBS restrictions for type 2 diabetes mellitus (T2DM) medicines

### 1 Purpose of Item

That the PBAC:

- 1.1 **Recommend** any changes to the PBS restrictions for sodium-glucose co-transporter 2 (SGLT2) inhibitors, dipeptidyl peptidase 4 (DPP4) inhibitors and glucagon-like peptide-1 receptor agonists (GLP-1 RAs) for the treatment of T2DM ([Appendix 1](#)).
- 1.2 **Advise** on the likely budget impact if the proposed restriction changes for GLP-1 RAs are recommended.
- 1.3 **Note** the pre-sub-committee response (PSCR) from a sponsor noting that sitagliptin moved to the F2 formulary in August 2022 and is now subject to price disclosure.
- 1.4 **Note** the DUSC advice, sponsor PSCRs and sponsor pre-PBAC responses for this item.
- 1.5 **Advise** whether the table at [Appendix 2](#) detailing PBS-subsidised T2DM medicine combinations should be incorporated into the PBS Schedule, noting the capacity of prescriber software to display this in a 'user friendly' form may be limited and that the table would require frequent updates to ensure its currency.
- 1.6 **Advise** whether the Department should pursue appropriate quality use of medicines educational activities on the PBS restrictions for T2DM medicines for prescribers, pharmacists and consumers that includes the [Appendix 2](#) table.

### 2 Background

#### ***Current PBS restrictions for T2DM medicines (abridged)***

- 2.1 Metformin, sulfonylureas, acarbose and most insulins have unrestricted PBS listings. Insulin detemir has a restricted benefit listing for type 1 diabetes.
- 2.2 DPP4 inhibitors, SGLT2 inhibitors, GLP-1 RAs and pioglitazone have Authority Required (STREAMLINED) listings for patients meeting certain criteria and for use in combination with specified medicines. Table 1 provides an overview of the PBS restrictions for the Authority Required diabetes medicines (at 1 February 2023). None of these classes of medicines were PBS subsidised for use as monotherapy.
- 2.3 Initiation on any of these Authority Required (STREAMLINED) medicines required patients to have, or have had, a HbA1c measurement greater than 7% despite treatment with specified medicines; OR if HbA1c measurement is clinically inappropriate, blood glucose levels above 10 mmol per L in more than 20% of tests over a 2-week period despite treatment with specified medicines.
- 2.4 GLP-1 RAs were not PBS-subsidised for use in combination with a DPP4 inhibitor, pioglitazone, or an SGLT2 inhibitor. The PBS restrictions for GLP-1 RAs differed from SGLT2 and DPP4 inhibitors in that dual therapy with metformin or a SU required contraindication/intolerance to a combination of metformin and a SU.

**Table 1: Abridged PBS restrictions for Authority required (Streamlined) T2DM medicines for T2DM indications (at 1 February 2023)**

Class	Drug	Dual oral with met or SU	Triple therapy with met + SU	With insulin (+/- met)	Triple therapy with met +
<b>DPP4 inhibitors (Gliptins)</b>	Alogliptin <sup>2</sup>	✓	X	X	X
	Linagliptin <sup>2,5</sup>	✓	✓	✓ <sup>3</sup>	SGLT2i
	Saxagliptin <sup>2,5</sup>	✓	✓	X	SGLT2i
	Sitagliptin <sup>2,5</sup>	✓	✓	✓ <sup>3</sup>	SGLT2i
	Vildagliptin <sup>2</sup>	✓	✓	✓ <sup>3</sup>	X
<b>SGLT2 inhibitors (Flozins)</b>	Dapagliflozin <sup>2</sup>	✓	✓	✓ <sup>3</sup>	DPP4i
	Empagliflozin <sup>2,4</sup>	✓	✓	✓ <sup>3</sup>	DPP4i
	Ertugliflozin <sup>4,8</sup>	✓	X	X	DPP4i
<b>Thiazolidinediones (TZD)</b>	Pioglitazone	✓ <sup>1</sup>	✓	✓ <sup>3</sup>	X
<b>GLP-1 RAs</b>	Dulaglutide	✓ <sup>1,6</sup>	✓	✓ <sup>7</sup>	X
	Semaglutide	✓ <sup>1</sup>	✓	✓ <sup>7</sup>	X

Abbreviations: DPP4i = dipeptidyl-peptidase-4 inhibitor, Met = metformin, SGLT2i = sodium-glucose cotransporter 2 inhibitor, SU = sulfonylurea.

## Notes:

1. Only if the patient is contraindicated or intolerant to metformin and a sulfonylurea.
2. Fixed dose combination products with metformin are also available for these medicines and listed for the same indications. FDCs are not subsidised for initial therapy.
3. Despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.
4. FDC with DPP4 inhibitor available.
5. FDC with SGLT2 inhibitor available.
6. Restricted to use in combination with metformin, not sulfonylurea.
7. Treatment must be in combination with metformin unless contraindicated or not tolerated.
8. Ertugliflozin with metformin FDC available as Supply Only from 1 January 2023.

### ***DUSC analysis of medicines for the treatment of type 2 diabetes – September 2022***

- 2.5 In July 2022, the PBAC expressed concern over the price difference between GLP-1 RAs and SGLT2 inhibitors, noting that this difference was based on the requirement for patients initiating dual therapy with a GLP-1 RA (in combination with metformin or a sulfonylurea) to be contraindicated or intolerant to the combination of metformin and a sulfonylurea (SU). The PBAC recommended a review of the utilisation of T2DM medicines, considering the current treatment pathways and extent of use outside the PBS restrictions for DPP4 inhibitors, SGLT2 inhibitors and GLP-1 RAs.<sup>1</sup>
- 2.6 In November 2022, PBAC considered the DUSC analysis on ‘*Medicines for the treatment of type 2 diabetes – September 2022*’.

<sup>1</sup> Department of Health and Aged Care, [Recommendations made by the PBAC – July 2022](#).

## Key findings

- 2.7 Total annual expenditure based on the published list prices on T2DM medicines had increased from around \$516 million in 2017-2018 to around \$756 million in 2021-22.
- 2.8 GLP-1 RAs were now the highest expenditure class of medicines on the PBS for the treatment of T2DM accounting for 26% of expenditure in 2021-22 (\$194 million).
- 2.9 There were several examples of apparent use outside the PBS restrictions:
- From 2017 to mid-2022, 18% of people initiating GLP-1 RA therapy were not supplied metformin, a SU or insulin prior to or at initiation, indicating clear use outside of the PBS restrictions. A further 57% were supplied only insulin, a SU, or metformin prior to or at initiation of a GLP-1 RA, indicating possible use outside of the PBS restrictions.
  - According to analysis of the prevalent population in 2021, almost 60% of people supplied a GLP-1 RA received this medicine in a regimen that is inconsistent with the PBS restrictions:
    - 42% were supplied a GLP-1 RA in combination with another GLP-1 RA, a DPP4 inhibitor, an SGLT2 inhibitor or a combination of these medicines.
    - 27% were supplied a GLP-1 RA without concomitant use of metformin, SU, or insulin.
    - 9.5% crossed both above categories and were supplied a GLP-1 RA without concomitant use of metformin, SU, or insulin and in combination with another GLP-1 RA, a DPP4 inhibitor, an SGLT2 inhibitor, or a combination of these medicines.
- 2.10 In 2021, around 15% of people supplied an SGLT2 inhibitor and 16% of people supplied a DPP4 inhibitor received these medicines without concomitant use of metformin, SU, or insulin, as required by the PBS restrictions.
- 2.11 In 2021, around 14% of people supplied an SGLT2 inhibitor and 7% of people supplied a DPP4 inhibitor received these medicines in combination with a GLP-1 RA, use which is inconsistent with the PBS restrictions.

## PBAC consideration – November 2022

- 2.12 The PBAC noted the substantial use of GLP-1 RAs outside of the PBS restrictions, including use as a first-line therapy, use without required concomitant therapies, and use in combination with DPP4 inhibitors and SGLT2 inhibitors. The PBAC also noted that there was some use of SGLT2 inhibitors and DPP4 inhibitors outside of the PBS restrictions, including likely use in monotherapy, as a first-line therapy, and use in combination with a GLP-1 RA. However, the PBAC considered that some of this use was likely to be in accordance with Australian and international clinical treatment guidelines and considered that there was growing misalignment between clinical guidelines and the PBS restrictions.
- 2.13 The PBAC noted that there was some prescribing of GLP-1 RAs concomitantly with DPP4 inhibitors and considered this to be both clinically inappropriate and non-cost-effective, as there is currently no evidence to support the use of this combination. The PBAC also noted some use of GLP-1 RAs with SGLT2 inhibitors, which has not been considered by the PBAC for cost-effectiveness. The PBAC considered that there may be some prescriber confusion regarding the restrictions (and clinical indications) for

T2DM medicines. The PBAC noted that the PBS restrictions for SGLT2 inhibitors and DPP4 inhibitors contain a 'Note' that these medicines are not subsidised for use in combination with a GLP-1 RA. The PBAC considered that it may be useful to move this requirement to an exclusionary 'Treatment Criterion' to aid in drawing this requirement to the attention of prescribers. The PBAC advised that it may also be appropriate for the Department to consider quality use of medicines educational activities on this topic for prescribers, pharmacists, and consumers.

- 2.14 Noting the significant use of GLP-1 RAs outside of the PBS restrictions (approximately 60%), the PBAC requested that the Department draft restriction changes to amend the restriction type for GLP-1 RAs from Authority Required (STREAMLINED) for all indications to Authority Required (telephone/electronic). The PBAC further requested that the restrictions for dual therapy with metformin/sulfonylurea include a requirement that patients initiating treatment with a GLP-1 RA be contraindicated or intolerant to an SGLT2 inhibitor, but that the requirement for contraindication or intolerance to a combination of metformin and a sulfonylurea could be removed.
- 2.15 The PBAC considered that it was appropriate that patients who had legitimately qualified for PBS-subsidised access under the previous restrictions for dual therapy with a GLP-1 RA and metformin/sulfonylurea should continue to have access to these medicines, without the requirement for contraindication or intolerance to an SGLT2 inhibitor.
- 2.16 The PBAC noted that dulaglutide is currently subsidised for dual therapy with metformin only, while semaglutide and exenatide were subsidised for use in combination with metformin or a sulfonylurea. The PBAC further noted that GLP-1 RAs are PBS-listed for triple therapy with metformin and a sulfonylurea. The PBAC considered that it would be appropriate to reduce the complexity of the restrictions for prescribers by aligning the restrictions and extending the listing of dulaglutide to include dual therapy with a sulfonylurea. The PBAC noted that this was within the listed indications for dulaglutide on the Australian Register of Therapeutic Goods (ARTG), and that the Product Information for both dulaglutide and semaglutide included a similar precaution regarding the risk of hypoglycaemia when used in combination with insulin or a sulfonylurea.<sup>2,3</sup> The PBAC considered that the cost-effectiveness of the use of dulaglutide in combination with a sulfonylurea, would be similar to that of semaglutide in combination with a sulfonylurea, and that the change would have a negligible impact on cost to the PBS.
- 2.17 The PBAC requested that the Department develop the draft restriction changes for GLP-1 RAs detailed above and provide costings for consideration at a future meeting.
- 2.18 The PBAC considered that changing the restriction type for GLP-1 RAs from the current Authority Required (STREAMLINED) to Authority Required (telephone/electronic) may have the unintended consequence of increasing SGLT2 inhibitor and DPP4 inhibitor use outside of the PBS restrictions, particularly use in monotherapy. The PBAC considered that it would be appropriate to review the utilisation of T2DM medicines

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<sup>2</sup> ARTG, [Product Information: Ozempic® \(semaglutide\) solution for injection](#), accessed: November 2022.

<sup>3</sup> ARTG, [Product Information: Trulicity \(dulaglutide RCH\) autoinjector](#), accessed: November 2022.

in 12-24 months to monitor the effectiveness of the GLP-1 RA restriction changes and any unintended consequences.

- 2.19 The PBAC recommended a price reduction of at least 15% in the cost of DPP4 inhibitors and SGLT2 inhibitors to account for the proportion of use outside the restrictions for which cost-effectiveness has not been considered.

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

- 2.20 Sponsors of all T2DM medicines were consulted on the DUSC analysis, following standard committee timelines and processes.
- 2.21 The sponsors of PBS-listed GLP-1 RAs, DPP4 inhibitors and SGLT2 inhibitors were consulted on the proposed restriction changes prior to the February 2023 DUSC meeting, provided with a copy of the DUSC Advice, and invited to provide a pre-PBAC response.

### **3 Current Situation**

#### ***Proposed PBS restriction changes***

- 3.1 The PBAC noted the draft restriction changes for SGLT2 inhibitors, DPP4 inhibitors and GLP-1 RAs.
- 3.2 The PBAC noted that the proposed restriction changes for DPP4 and SGLT2 inhibitors aim to reduce complexity and provide clarity, and that these changes were generally supported by sponsor companies and the DUSC. The PBAC recommended that the number of restriction and item codes for each product should be reduced to one. This would involve the deletion of one item code for each SGLT2 inhibitor and DPP4 inhibitor product that currently have two item codes (noting that alogliptin and vildagliptin products only have a single item code). The proposed restrictions include a treatment criterion listing the medicines with which they are not to be used in combination. The PBAC noted that these restriction changes aim to improve compliance with the PBS restrictions.
- 3.3 The proposed restrictions for DPP4 and SGLT2 inhibitors did not require inadequate response (defined by glycaemic measurement) to dual therapy for patients to commence triple therapy with metformin and a sulfonylurea.
- 3.4 The sitagliptin Lupin brand was currently not registered with the Therapeutic Goods Administration (TGA) for use in combination with SGLT2 inhibitors, unlike the other sitagliptin brands. It has a PBS-listing for continuation of combination therapy with an SGLT2 inhibitor but not initiation of this therapy. The PBS Restrictions Section have advised that they are consulting the sponsor regarding a fix for this issue. The proposed restriction changes assumed that the TGA indications are the same across the sitagliptin brands.
- 3.5 Following the listing of a first new brand of sitagliptin on 1 August 2022, sitagliptin moved to the F2 formulary and a 25% price reduction was applied. This medicine was now subject to price disclosure pricing mechanisms.

- 3.6 The proposed changes to the GLP-1 RA restrictions included:
- changing the authority type to Authority Required (electronic/telephone)
  - requiring contraindication/intolerance to an SGLT2 inhibitor prior to initiation of dual therapy with metformin or a sulfonylurea
  - addition of a treatment criterion specifically excluding PBS-subsidised use in combination with DPP4 inhibitors, SGLT2 inhibitors and pioglitazone
  - reducing the number of item and restriction codes to one
  - expanding the PBS listing for dulaglutide to include use in dual therapy with a sulfonylurea (if contraindicated/intolerant to an SGLT2 inhibitor).
- 3.7 The proposed restriction changes allow patients who have previously received PBS-subsidised treatment for T2DM with a GLP-1 RA, and who met the requirements of the previous restriction, to continue using a GLP-1 RA.
- 3.8 The PBAC noted that under the proposed restrictions patients who are inadequately responsive to dual therapy with metformin and an SGLT2 inhibitor (rather than contraindicated/intolerant to SGLT2 inhibitors) have several triple therapy medicine options (i.e., addition of a sulfonylurea, insulin, or a DPP4 inhibitor), or could cease the SGLT2 inhibitor and progress to dual therapy with metformin in combination with either a SU or insulin, and then to triple therapy by adding a GLP-1 RA if required.
- 3.9 In November 2022, the PBAC recommended consumer and prescriber educational activities to promote the PBS subsidy rules for T2DM medicines. In February 2023, the DUSC considered that this could include a table of permitted/non-permitted combinations for subsidy, and that educational materials should include generic medicines and brand names as some prescribers may not be aware that they are prescribing medicines from the same class.

### ***Budget impact***

- 3.10 The PBAC noted that the net saving associated with the proposed GLP-1 RA restriction changes to the R/PBS is estimated to be █████ in 2023, increasing to █████ in 2028 (total of █████ over 2023-2028), based on the effective prices of GLP-1 RAs (Table 2). The PBAC noted that there would be an associated cost to Services Australia from the restriction changes.

**Table 2: Net saving to R/PBS for proposed GLP-1 RA restriction changes based on effective prices – base case**

Table redacted.

Source: Cost model workbook – GLP-1 RA restriction change - Base case.

- 3.11 The financial estimates are based on a linear projection of GLP-1 RA script numbers, based on the average monthly increase in scripts between July 2021 to June 2022 for each item code. Although data were available on prescriptions supplied up to October 2022, these data were not used to estimate the average monthly increase in scripts as script volumes from July 2022 were presumed to be impacted by product shortages ([Figure 1](#)).

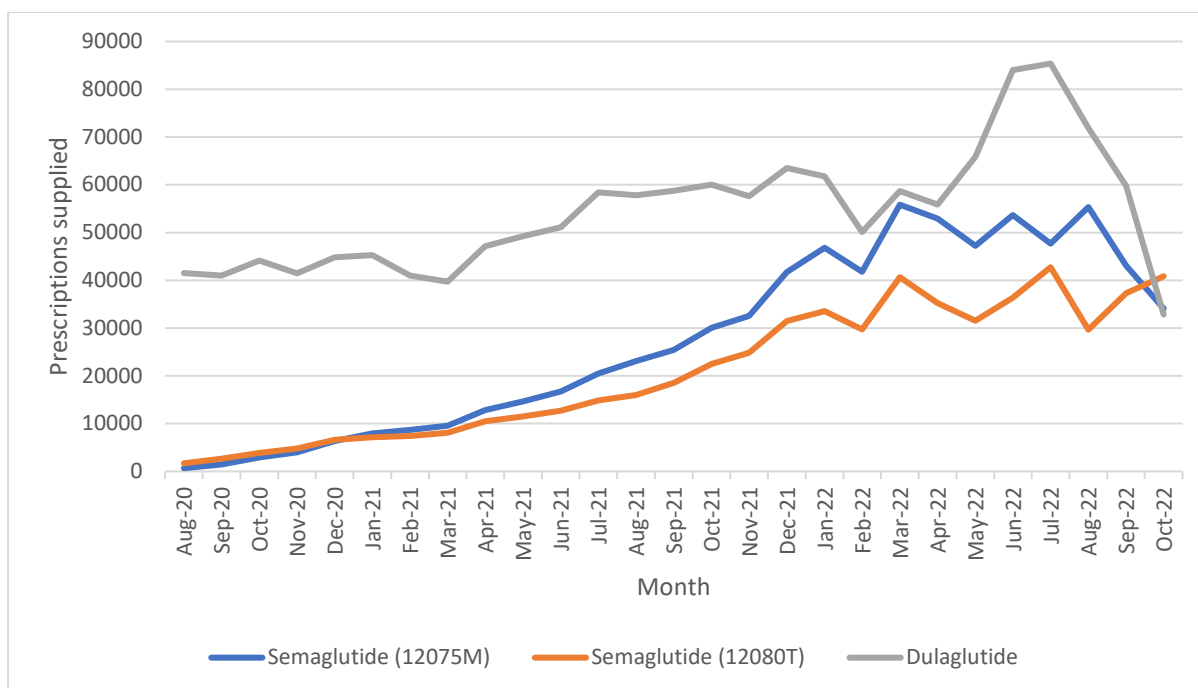


Figure 1: PBS prescriptions supplied for GLP-1 RAs (August 2020 to October 2022)

Source: Cost model workbook – GLP-1 RA restriction change - Base case, Worksheet: Data 2, based on Services Australia data.

- 3.12 Services Australia data on prescriptions supplied through the PBS from November 2021 to October 2022 were used to estimate script numbers for 2022. For dulaglutide and semaglutide, between November 2022 to October 2023, script volumes were held constant at the average monthly script volume between July 2021 to June 2022, to model product shortages. An implementation date for the restriction changes of 1 July 2023 was assumed.
- 3.13 The financial estimates do not include exenatide (item codes: 3423E and 3424F), as exenatide was delisted from the PBS from 1 February 2023.
- 3.14 The financial estimates assumed that patients who are no longer able to receive subsidised access to a GLP-1 RA will be prescribed an SGLT2 inhibitor. This was considered the closest comparator and most likely medicine to be substituted in clinical practice. In practice, patients may alternatively receive PBS-subsidised metformin, sulfonylurea, acarbose, DPP4 inhibitor or insulin, or a private prescription for a GLP-1 RA, but likely proportions of use were considered difficult to estimate.
- 3.15 Data from the DUSC analysis was used to estimate the proportion of scripts that would be affected, i.e., GLP-1 RA scripts that would be substituted by an SGLT2 inhibitor script. Based on the DUSC analysis, 59.5% of the current and future scripts were considered to be for use outside the PBS restrictions and would be affected. For the remaining 40.5% of scripts, data on the use of metformin, sulfonylureas, and insulin prior to initiation of GLP-1 RAs between 2017-2021 was used to estimate the proportion of GLP-1 RA scripts for use in dual therapy with metformin/sulfonylurea, compared to triple therapy and dual therapy with insulin. Current GLP-1 RA script volumes associated with dual therapy with metformin/sulfonylurea were assumed to

continue unchanged. In practice, they should reduce due to cessation, switching and patient death, as well as possible reductions from patients who did not meet the original eligibility criteria.

- 3.16 For future scripts associated with GLP-1 RA dual therapy with metformin/sulfonylurea, 75% were assumed to be 'affected', based on an estimated contraindication/intolerance rate of 25% for SGLT2 inhibitors. The estimated rate of contraindication/intolerance to SGLT2 inhibitors was based on the Product Information for dapagliflozin<sup>4</sup> and empagliflozin<sup>5</sup> including the main contraindications, rates of discontinuations from clinical trials, and rates of adverse events (AEs). The main contraindications for SGLT2 inhibitors include: eGFR <30 mL/min/1.73 m<sup>2</sup>; severe hepatic impairment (dapagliflozin); age >85 years (empagliflozin); hypersensitivity to excipients; history/risk of hypotension/volume depletion/dehydration; pregnancy and breastfeeding. The rate of discontinuation in clinical trials for dapagliflozin was 4.3%; however, the rate of AEs was much higher with approximately 30% of patients experiencing the most common AEs of hypoglycaemia, back pain, polyuria, and genital and urinary tract infections. For empagliflozin, the rate of discontinuation in clinical trials was around 5%, and AEs was around 20% across pooled studies.
- 3.17 DUSC analysis data on quarterly script volumes and patient numbers between July 2021 to June 2022 were used to estimate average scripts/patient/year for GLP-1 RAs (10.7) and SGLT2 inhibitors (10.9).
- 3.18 Table 3 summarises the key assumptions used to develop the financial estimates, including the likely magnitude of impact on the estimates.

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<sup>4</sup> Australian Register of Therapeutic Goods (ARTG), [Dapagliflozin \(Forxiga\) 10 mg Product Information](#), accessed November 2022.

<sup>5</sup> ARTG, [Empagliflozin \(Jardiance\) 10 mg/ 25 mg](#), accessed November 2022.

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Table 3: Key assumptions and values used to estimate the financial impact of the proposed GLP-1 RA restriction changes

Assumption/Variable	Base case value Source	Impact on estimates	Test in sensitivity analysis?
Implementation date for restriction changes	1 July 2023 Source: Department estimate based on presumed March 2023 PBAC recommendation	Negligible in base case, due to product shortages for semaglutide and dulaglutide modelled to continue until 1 November 2023.	No
Linear projection of GLP-1 RA scripts	Average monthly increase in scripts by item code: <ul style="list-style-type: none"> <li>• Semaglutide: 12075M = 3077, 12080T = 1972.</li> <li>• Dulaglutide: 11364D = 2742.</li> </ul> Source: Services Australia data on monthly script volumes July 2021-June 2022. Timeframe selected aimed to avoid the reduction in scripts post July 2022 due to product shortages but is considered to include some impact of product shortages in early 2022.	High	Yes, using Services Australia data on monthly script volumes September 2021- August 2022. Data to October 2022 were not used as this resulted in a decline in dulaglutide use over time. <ul style="list-style-type: none"> <li>• Semaglutide: 12075M = 2687, 12080T = 1138</li> <li>• Dulaglutide: 11364D = 1173</li> </ul>
Duration of product shortages for semaglutide and dulaglutide	12 months (November 2022-October 2023) Source: Department estimate	Likely low.	No
Use of GLP-1 RAs outside the PBS restrictions	59.5% Source: DUSC analysis. Estimate of the proportion of patients supplied a GLP-1 RA: <ul style="list-style-type: none"> <li>• in combination with another GLP-1 RA, a DPP4 inhibitor, an SGLT2 inhibitor, or a combination of these; and/or</li> <li>• not in combination with metformin, a sulfonylurea or insulin.</li> </ul>	Moderate to high. Base case estimate likely favours increased PBS savings. This may be an underestimate as it does not consider use of prior therapies in determining whether use is outside the restrictions. Conversely, it may be an overestimate due to misclassification of patients who have switched medicines. Prescriber compliance with the restrictions is also unlikely to be 100%.	Yes, reduce by 10% to 49.5%
Rate of contraindication/intolerance to SGLT2 inhibitors	25% Source: Department estimate, based on Product Information for dapagliflozin and empagliflozin, including listed contraindications, rate of discontinuations in clinical trials, and rates of adverse events.	Low. Base case estimate likely favours reduced PBS savings.	Yes, reduce from 25% to 10%.

3.19 To understand how the projected GLP-1 RA script volumes compare to the total T2DM population, a projection of T2DM patient numbers was made based on the data from the DUSC analysis (quarterly patient numbers between 2017 to 2021), which produced an estimated 5.6% annual growth rate in T2DM patients. The projection estimates that script volumes for GLP-1 RAs will increase from 1.7 million in 2022 to 7.0 million in 2028, and patients supplied GLP-1 RAs will increase from around 160,000 in 2022 (13% of T2DM patients) to 650,000 in 2028 (38% of T2DM patients) (Table 4). This estimate may seem high; however, it is difficult to estimate the level of current and future subsidised use of GLP-1 RAs outside of the PBS restrictions, including use in weight management, without the proposed restriction changes. It should be noted that current eligibility for PBS-subsidised dual therapy with a GLP-1 RA is not limited to patients at high CV risk, but only requires contraindication/intolerance to a combination of metformin and a sulfonylurea, and HbA1c >7%. With greater awareness of the CV benefits associated with SGLT2 inhibitors and GLP-1 RAs, these medicines are expected under the current restrictions to take precedence as first-line dual therapies for T2DM over sulfonylureas and DPP4 inhibitors. In addition, the following studies provide support for the estimate of 38% use of GLP-1 RAs among T2DM patients in 2028:

- An analysis from a nationally representative US dataset based on clinical and laboratory data, that indicated that around 33% of patients with type 2 diabetes should be eligible for treatment with GLP-1 RAs, based on established or high risk of CVD.<sup>6</sup>
- A study in Scotland using a nationwide diabetes register, which estimated that 30.4% of patients with T2DM would be recommended to start therapy with either a GLP-1 RA or SGLT2 inhibitor based on the 2019 European Society of Cardiology guidelines for CV risk management. This estimate was based on patients with high/very high CV risk and either on no T2DM therapy or metformin monotherapy.<sup>7</sup>
- A US study which showed a 348% increase in GLP-1 RA prescriptions over the 4-year period from 2014-2017.<sup>8</sup>

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<sup>6</sup> Nargesi, A.A. et al (2021) 'Contemporary National Patterns of Eligibility and Use of Novel Cardioprotective Antihyperglycemic Agents in Type 2 Diabetes Mellitus', J AM Heart Assoc, 10(13):e021084.

<sup>7</sup> Caparrotta, T et al. (2020) 'Prescribing Paradigm Shift? Applying the 2019 European Society of Cardiology-Led Guidelines on Diabetes, Prediabetes, and Cardiovascular Disease to Assess Eligibility for Sodium-Glucose Cotransporter 2 Inhibitors or Glucagon-Like Peptide 1 Receptor Agonists as First-Line Monotherapy (or Add-on to Metformin Monotherapy) in Type 2 Diabetes in Scotland', Diabetes Care, 43(9): 2034-41.

<sup>8</sup> Sumarsono, A et al (2020) 'Medicaid expansion and utilization of antihyperglycaemic therapies', Diabetes care, 43(11): 2684-2690.

**Table 4: Projection of GLP-1 RA scripts, including as a proportion of the T2DM population (2022 to 2028)**

Year	Projected annual GLP-1 scripts		Total projected GLP-1 scripts	Projected GLP-1 patients	Projected T2DM patients	% GLP-1/ T2DM patients
	Semaglutide	Dulaglutide				
2022	997,127	750,635	1,747,762	163,342	1,231,554	13.3%
2023	981,746	755,474	1,737,220	162,357	1,300,522	12.5%
2024	1,481,523	1,026,908	2,508,430	234,433	1,373,351	17.1%
2025	2,208,471	1,421,720	3,630,190	339,270	1,450,258	23.4%
2026	2,935,419	1,816,532	4,751,950	444,107	1,531,473	29.0%
2027	3,617,313	2,211,344	5,828,656	544,734	1,617,235	33.7%
2028	4,389,315	2,606,156	6,995,470	653,782	1,707,800	38.3%

Source: Cost model workbook – GLP-1 RA restriction change - Base case, Worksheets: Data 3 & Data 5.

### **Budget impact - Sensitivity analyses**

3.20 The following tables show the net savings to the R/PBS for the proposed GLP-1 RA restriction changes between 2023 to 2028, based on the following sensitivity analyses:

- Table 5: Reduction in the average monthly increase in GLP-1 RA script numbers, by using Services Australia script data from September 2021 to August 2022.
- Table 6: Reduction in the estimated use of GLP-1 RAs outside of the PBS restrictions from 59.5% to 49.5%.
- Table 7: Reduction in the rate of contraindication/intolerance to SGLT2 inhibitors from 25% to 10%.

3.21 The budget estimates are relatively insensitive to changes in the rate of contraindication/intolerance to SGLT2 inhibitors [REDACTED]. Reducing the estimation of use of GLP-1 RAs outside the PBS restrictions (which would include prescriber compliance with the new restrictions) had a moderate to high impact on the estimated budget saving [REDACTED]. Reducing the projected script volumes for GLP-1 RAs had a high impact on the estimates [REDACTED]. A sensitivity analysis examining the impact of all three of the above analyses (Attachment H) showed a [REDACTED] in the estimated budget saving over the six years (data not shown).

For more detail on PBAC’s view, see section 5 PBAC outcome.

**Table 5: Net saving to R/PBS for proposed GLP-1 RA restriction changes based on effective prices – sensitivity analysis based on reduced average monthly increase in GLP-1 RA script numbers**

Table redacted.

Source: Cost model workbook – GLP-1 RA restriction change – Sensitivity analysis script numbers.

**Table 6: Net saving to R/PBS for proposed GLP-1 RA restriction changes based on effective prices – sensitivity analysis based on reduced estimation of GLP-1 RA use outside restrictions**

Table redacted.

Source: Cost model workbook – GLP-1 RA restriction change – Sensitivity analysis use outside restrictions.

**Table 7: Net saving to R/PBS for proposed GLP-1 RA restriction changes based on effective prices – sensitivity analysis based on reduced rate of contraindication/intolerance to SGLT2 inhibitors**

Table redacted.

Source: Cost model workbook – GLP-1 RA restriction change – Sensitivity analysis SGLT2 contraindication.

## **4 Sponsor comments**

- 4.1 The PBAC noted the PSCRs and pre-PBAC comments from sponsors.
- 4.2 The PBAC noted that most sponsors supported the simplification of the PBS restrictions for T2DM medicines.
- 4.3 The PBAC noted the PSCR from one sponsor noted that sitagliptin had moved to the F2 formulary in August 2022 and is now subject to price disclosure.

## **5 PBAC Outcome**

- 5.1 The PBAC noted the proposed restriction changes for DPP4 inhibitors and SGLT2 inhibitors and considered that it was appropriate to reduce the number of item and restriction codes for each product for the T2DM indication to one.
- 5.2 The PBAC was requested to advise whether a table detailing PBS-subsidised T2DM medicine combinations should be included in the PBS Schedule, Explanatory Notes, with a website link to the guidance included as Administrative Advice in the PBS restrictions for T2DM medicines. The PBAC did not recommend inclusion of such a table in the PBS Schedule, noting that it may be difficult to ensure the currency of the table given the frequent changes to the T2DM medicine market. However, the PBAC considered that the table, with minor revisions, could form part of the consultation process with prescribers on the PBS restrictions for T2DM medicines. [Appendix 2](#) shows the revised table incorporating PBAC amendments.
- 5.3 The PBAC recommended removal of the requirement for patients to be contraindicated to metformin, to use DPP4 inhibitors (linagliptin, sitagliptin and vildagliptin only), SGLT2 inhibitors or GLP-1 RAs in dual therapy with insulin. The PBAC considered that it was clinically unlikely that patients would be on insulin therapy without concomitant metformin unless the patient was contraindicated or intolerant to metformin.
- 5.4 The PBAC noted that the proposed restrictions for DPP4 inhibitors and SGLT2 inhibitors did not require inadequate response to dual therapy for patients to commence triple therapy with metformin and a sulfonylurea. The PBAC considered that from a clinical perspective it was unlikely that patients would proceed to triple therapy without trialling dual therapy first. The PBAC also considered that the requirement for patients to inadequately respond to dual therapy with metformin and an SGLT2 inhibitor or DPP4 inhibitor prior to commencing triple therapy with metformin, an SGLT2 inhibitor and a DPP4 inhibitor, could also be removed from DPP4 inhibitor and SGLT2 inhibitor single drug formulations to simplify the restrictions.

- 5.5 The PBAC noted that with the listing of a first new brand of sitagliptin on 1 August 2022, sitagliptin brands moved to the F2 formulary (taking a 25% price reduction) and were now subject to price disclosure pricing mechanisms. Regarding the November 2022 PBAC recommendation for a 15% price reduction to DPP4 inhibitors and SGLT2 inhibitors to account for use outside of the PBS restrictions, the PBAC recommended that the 15% price reduction should not apply to sitagliptin brands in the F2 formulary. The PBAC considered that the recent 25% price reduction was sufficient to restore cost-effective use of sitagliptin.
- 5.6 The PBAC noted the financial estimates and sensitivity analyses provided for the proposed restriction changes for GLP-1 RAs. The PBAC considered that the financial estimates were highly uncertain but noted the difficulties in predicting the likely future use of GLP-1 RAs due to product shortages and prescriber compliance with the proposed restrictions, which were key drivers of the financial estimates.
- 5.7 The PBAC recommended that the authority type for GLP-1 RAs, for therapy initiation for all indications, be changed from Authority Required (STREAMLINED) to Authority Required (telephone/electronic), but that continuing access be via a streamlined authority listing. In making this recommendation, the PBAC noted the high use of GLP-1 RAs outside of the PBS restrictions, their higher cost versus alternative treatments that are no worse at reducing HbA1c levels, and the DUSC's concern regarding the administrative burden on prescribers associated with the proposed change in authority type for GLP-1 RAs to Authority Required (telephone/electronic) for all prescriptions.
- 5.8 The PBAC considered the option of limiting initiation of prescribing of GLP-1 RAs to endocrinologists but noted that patients with T2DM are predominantly managed by GPs in Australia and most GLP-1 RAs are prescribed by GPs. The PBAC considered that limiting initiation of GLP-1 RA prescribing to endocrinologists may impact on equity of access, particularly for patients in rural and remote areas.
- 5.9 The PBAC noted that the proposed contraindication/intolerance criterion for GLP-1 RAs stated that the patient must have a contraindication or intolerance to an SGLT2 inhibitor 'requiring permanent treatment discontinuation'. The PBAC considered that this wording was appropriate, as continuing access to GLP-1 RAs would be via a streamlined authority rather than a telephone/electronic authority, reducing opportunities for patients requiring temporary SGLT2 inhibitor treatment discontinuation to consider a re-trial of an SGLT2 inhibitor. The PBAC also considered that this may reduce the use of GLP-1 RAs in combination with SGLT2 inhibitors, which has not been assessed by the PBAC for cost-effectiveness.
- 5.10 The PBAC noted that the results from the DUSC analysis indicated that up to 60% of GLP-1 RA use was outside of the PBS restrictions. The PBAC considered that as patients currently on GLP-1 RA therapy would have access to this medicine through the continuing Authority Required (STREAMLINED) restriction, the recommended restriction changes may have little impact on current use of GLP-1 RAs outside of the restrictions, but that new use should be more in line with the PBS restrictions.
- 5.11 The PBAC considered that the financial estimates may need to be revised to remove estimates associated with patients currently using GLP-1 RAs outside of the PBS restrictions moving to SGLT2 inhibitor therapy. The PBAC further noted that prescriber

compliance with the proposed PBS restrictions for GLP-1 RAs was a key driver of the financial estimates, and that the availability of an Authority Required (STREAMLINED) listing for continuation of therapy may reduce prescriber compliance with the restrictions. The PBAC recommended that the effectiveness of the restriction changes and compliance with the restrictions be investigated as part of a future DUSC analysis.

- 5.12 The PBAC recalled that in November 2022, it recommended that the PBS restrictions for GLP-1 RAs for dual therapy with metformin/sulfonylurea be amended to remove the requirement for contraindication/intolerance to a combination of metformin and a sulfonylurea and replace this with a requirement for contraindication/intolerance to an SGLT2 inhibitor. In making this recommendation the PBAC had noted that the cost of these medicines was high compared to alternative treatments that had a similar place in T2DM therapy, such as SGLT2 inhibitors. The PBAC agreed with the proposed restrictions changes for GLP-1 RAs; however, noting the place of GLP-1 RAs in clinical guidelines, the PBAC recommended expanding the listings of GLP-1 RAs to allow dual therapy with metformin/sulfonylurea in patients inadequately responsive to SGLT2 inhibitor therapy, provided that the SGLT2 inhibitor was ceased. The PBAC was satisfied that GLP-1 RAs would be suitably cost-effective in this indication at the current price.
- 5.13 The PBAC noted that in addition to their listings for T2DM, dapagliflozin is PBS-listed for chronic kidney disease (CKD) and chronic heart failure (CHF) and empagliflozin is PBS-listed for CHF. Therefore, under the proposed amended restrictions, patients with CKD/CHF and comorbid T2DM may be prescribed both an SGLT2 inhibitor and a GLP-1 RA, if they are inadequately responsive to an SGLT2 inhibitor for T2DM management. The PBAC considered that it may be beneficial to clarify this in the PBS restrictions for GLP-1 RAs, under Administrative Advice.
- 5.14 The PBAC recommended that use of GLP-1 RAs in triple therapy with metformin and a sulfonylurea and use in combination with insulin, be made second-line to SGLT2 inhibitor therapy, i.e. that a requirement for patients to be contraindicated, intolerant or inadequately responsive to SGLT2 inhibitor therapy be added to the PBS restrictions for all T2DM indications for GLP-1 RAs. The PBAC recalled that both SGLT2 inhibitors and GLP-1 RAs had been PBS-listed based on a series of non-inferiority comparisons originating from insulin,<sup>9</sup> and that no submission for these medicines had received a positive recommendation based on a clinical claim of superiority. The PBAC further recalled that as the price of SGLT2 inhibitors was reduced in 2015, this meant that SGLT2 inhibitors were a more cost-effective intervention in these indications. The PBAC noted that the financial estimates would need to be revised to reflect this recommendation.
- 5.15 The PBAC noted the current low cost and use of pioglitazone and recommended that pioglitazone could change to a Restricted Benefit listing for T2DM. The PBAC noted that this would provide an additional first-line therapy for patients who are contraindicated or intolerant to metformin.

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<sup>9</sup> Department of Health and Aged Care, Post-market Review of Products Used in the Management of Diabetes, [Part 3: Type 2 Diabetes Medicines](#), Final Report, October 2014, Part 5 – PBS Listing of Type 2 Diabetes Medicines (ToR 3).

- 5.16 The PBAC noted that metformin combinations with ertugliflozin became Supply Only through the PBS on 1 January 2023. As these items can no longer be prescribed, the PBAC recommended that no changes be made to these listings.
- 5.17 The PBAC agreed in-principle to the revised restrictions for pioglitazone, SGLT2 inhibitors, DPP4 inhibitors and GLP-1 RAs provided at [Appendix 1](#). However, the PBAC considered that there may be an opportunity to further simplify the wording of the restrictions and recommended that the Department consult relevant professional groups on the proposed restriction wording, such as the Australian Diabetes Society (ADS), Royal Australian College of General Practitioners (RACGP), Diabetes Australia, and the Australian College of Nursing (ACN) (diabetes education). The PBAC considered that it would be important in this consultation process to note that PBS restrictions may differ from clinical guidelines due to the consideration of the cost-effectiveness of comparator treatments.
- 5.18 The PBAC advised the Department that it would be appropriate to pursue quality use of medicines educational activities on the PBS restrictions for T2DM medicines for prescribers, pharmacists, and consumers in concert with the implementation of restriction changes. The PBAC considered that a table detailing PBS-subsidised T2DM medicine combinations, such as that at [Appendix 2](#), could form part of this process. The PBAC considered that professional input into the design of educational tools would be advantageous.

**Outcome:**

Advice Provided

**Appendices**

Appendix 1	Recommended listing changes for SGLT2 inhibitors, DPP4 inhibitors, GLP-1 RAs and pioglitazone
Appendix 2	Example General Statement for T2DM Medicines

## Appendix 1 – Recommended listing changes for SGLT2 inhibitors, DPP4 inhibitors, GLP-1 RAs, and pioglitazone

Amend the existing PBS listings as follows, after consultation with prescriber and consumer groups:

### SGLT2 inhibitors

#### PBS-listings for Dapagliflozin and Empagliflozin

Category / Program: GENERAL – General Schedule (Code GE)					
MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
<b>DAPAGLIFLOZIN</b>					
dapagliflozin 10 mg tablet, 28	10011X MP NP 11291G MP	1	28	5	Forxiga
<b>EMPAGLIFLOZIN</b>					
empagliflozin 10 mg tablet, 30	10206E MP NP 11314L MP	1	30	5	Jardiance
empagliflozin 25 mg tablet, 30	10202Y MP NP 11281R MP	1	30	5	Jardiance
New restriction to replace:					
Dapagliflozin and empagliflozin Authority Required (STREAMLINED) codes: 7506 (dual therapy with either metformin/sulfonylurea), 4991 (in combination with insulin), 5629 (triple therapy with metformin + a sulfonylurea), 7528 (Initial tx. with metformin + DPP4 gliptin), 7495 (Cont. tx with metformin + DPP4 gliptin)					
<b>Restriction Summary [New] / ToC: [New]: Authority Required (STREAMLINED)</b>					
8995	<b>Indication:</b> Diabetes mellitus type 2				
	<b>Clinical criteria:</b>				
New CC	The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin.				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
New CC	The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
New CC	The treatment must not be prescribed in combination with each of: a GLP-1 receptor agonist, another SGLT2 inhibitor.				
	<b>Prescribing Instructions:</b>				
	Definition: A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels				

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New PI1	<p>greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.</p> <p>Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:</p> <p>(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),</p> <p>(b) Red cell transfusion within the previous 3 months.</p> <p>Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contra-indications in the patient's medical records.</p>
7703	<p><b>Administrative Advice:</b></p> <p><b>Continuing Therapy Only:</b></p> <p>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.</p>
New AA1	<p><b>Administrative Advice:</b></p> <p>Abbreviations used in the restriction are as follows:</p> <p>SGLT2 – sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')</p> <p>DPP4 – dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')</p> <p>GLP-1 – glucagon-like peptide-1 receptor agonist (e.g., dulaglutide, semaglutide)</p> <p>Where acarbose or pioglitazone are prescribed as part of therapy, the listed combinations in the restriction may also include these medicines.</p>

**PBS-listings for Metformin combinations with Dapagliflozin and Empagliflozin**

Category / Program: GENERAL – General Schedule (Code GE)					
MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
<b>DAPAGLIFLOZIN + METFORMIN</b>					
dapagliflozin 5 mg tablet + metformin hydrochloride 1 g modified release tablet, 56	10510E MP NP 11300R MP	1	56	5	Xigduo XR 5/1000
dapagliflozin 10 mg tablet + metformin hydrochloride 1 g modified release tablet, 56	10515K MP NP 11313K MP	1	56	5	Xigduo XR 10/1000
dapagliflozin 10 mg tablet + metformin hydrochloride 500 mg modified release tablet, 56	10516L MP NP 11270E MP	1	56	5	Xigduo XR 10/500
<b>EMPAGLIFLOZIN + METFORMIN</b>					
empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60	10626G MP NP 10650M MP	1	60	5	Jardiamet 5 mg/500 mg
empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60	10627H MP NP 10649L MP	1	60	5	Jardiamet 5 mg/1000 mg
empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60	10633P MP NP 10639Y MP	1	60	5	Jardiamet 12.5 mg/ 500 mg
empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60	10677Y MP NP 10640B	1	60	5	Jardiamet 12.5 mg/1000 mg

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	MP				
<p>New restriction to replace:</p> <p>Empagliflozin + metformin Authority Required (STREAMLINED) codes:            5953 (this FDC product alone),            5966 (Cont. tx of any regimen containing the 2 drugs),            5798 (triple therapy with this FDC product + a sulfonylurea),            5657 (triple therapy with this FDC product + insulin),            7498 (Initial tx triple therapy with this FDC product + a DPP4 gliptin; present in the second set of PBS item codes specified above)            7492 (Cont. tx triple therapy with this FDC product + a DPP4 gliptin),</p> <p>and</p> <p>Dapagliflozin + metformin Authority Required (STREAMLINED) codes:            5631 (this FDC product alone) – different code to 5953 because one concept is written a Prescribing Instruction in one and as a NOTE in the other restriction.            5739 (Cont. tx of any regimen containing the 2 drugs),            5798 (triple therapy with this FDC product + a sulfonylurea),            5657 (triple therapy with this FDC product + insulin),            7498 (Initial tx. triple therapy with this FDC product + a DPP4 gliptin; present in the second set of PBS item codes specified above),            7492 (Cont. tx. triple therapy with this FDC product + a DPP4 gliptin),</p>					
<b>Restriction Summary [New] / ToC: [New]: Authority Required (STREAMLINED)</b>					
8995	<b>Indication:</b> Diabetes mellitus type 2				
	<b>Clinical criteria:</b>				
New CC	The condition must be inadequately responsive to metformin				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
New CC	The treatment must not be prescribed in combination with each of: a GLP-1 receptor agonist, another SGLT2 inhibitor.				
	<b>Prescribing Instructions:</b>				
	Definition: A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.				
New P11	Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies: (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies), (b) Red cell transfusion within the previous 3 months. Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contra-indications in the patient's medical records.				
	<b>Administrative Advice:</b>				
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>Administrative Advice:</b> Abbreviations used in the restriction are as follows:				

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New AA1	<p>SGLT2 – sodium glucose transporter-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 (e.g., dulaglutide, semaglutide)</p> <p>Where acarbose or pioglitazone are prescribed as part of therapy, the listed combinations in the restriction may also include these medicines.</p>
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**PBS-listings for DPP4 inhibitor combinations with SGLT2 inhibitors**

Category / Program: GENERAL – General Schedule (Code GE)					
MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№. of Rpts	Available brands
<b>SAXAGLIPTIN + DAPAGLIFLOZIN</b>					
saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28	11286B MP 11305B MP NP	1	28	5	Qtern 5/10
<b>EMPAGLIFLOZIN + LINAGLIPTIN</b>					
empagliflozin 10 mg + linagliptin 5 mg tablet, 30	11269D MP 11310G MP NP	1	30	5	Glyxambi
empagliflozin 25 mg + linagliptin 5 mg tablet, 30	11303X MP 11298P MP NP	1	30	5	Glyxambi
<b>ERTUGLIFLOZIN + SITAGLIPTIN</b>					
ertugliflozin 5 mg + sitagliptin 100 mg tablet, 28	11561L MP 11579K MP NP	1	28	5	Steglujan 5/100
ertugliflozin 15 mg + sitagliptin 100 mg tablet, 28	11583P MP 11578J MP NP	1	28	5	Steglujan 15/100
<p>New restriction to replace:</p> <p>Authority Required (STREAMLINED) codes:                      7524 (Initial tx with this FDC product + metformin),                      7556 (Cont. tx with this FDC product + metformin)</p>					
<b>Restriction Summary [New] / ToC: [New]: Authority Required (STREAMLINED)</b>					
8995	<b>Indication:</b> Diabetes mellitus type 2				
	<b>Clinical criteria:</b>				
New CC	The treatment must be triple combination therapy limited to this drug with metformin				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
New CC	The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DPP-4 inhibitor, an SGLT2 inhibitor				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
New CC	The treatment must not be prescribed in combination with each of: a GLP-1 receptor agonist, insulin, another SGLT2 inhibitor, another DPP4 inhibitor				
	<b>Prescribing Instructions:</b>				

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New PI1	<p>Definition: A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.</p> <p>Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies: (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies), (b) Red cell transfusion within the previous 3 months. Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contra-indications in the patient's medical records.</p>
7703	<p><b>Administrative Advice:</b> <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.</p>
New AA1	<p><b>Administrative Advice:</b> Abbreviations used in the restriction are as follows: SGLT2 – sodium glucose transporter-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 (e.g., dulaglutide, semaglutide)</p> <p>Where acarbose or pioglitazone are prescribed as part of therapy, the listed combinations in the restriction may also include these medicines.</p>

**PBS-listings for Ertugliflozin**

<b>Category / Program:</b> GENERAL – General Schedule (Code GE)					
MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ERTUGLIFLOZIN					
ertugliflozin 5 mg tablet, 28	11577H MP 11585R MP NP	1	28	5	Steglatro 5
ertugliflozin 15 mg tablet, 28	11570Y MP 11571B MP NP	1	28	5	Steglatro 15
<p>New restriction to replace:</p> <p>Authority Required (STREAMLINED) codes: 7528 (Initial tx. triple therapy with metformin + DPP4 gliptin), 7495 (Cont. tx. triple therapy with metformin + DPP4 gliptin), 7506 (dual therapy with either metformin/sulfonylurea)</p> <p>(Note: Ertugliflozin is not subsidised for use in combination with insulin)</p>					
<b>Restriction Summary [New] / ToC: [New]: Authority Required (STREAMLINED)</b>					
8995	<b>Indication:</b> Diabetes mellitus type 2				
	<b>Clinical criteria:</b>				
New CC	The treatment must be used in combination with at least one of: metformin, a sulfonylurea				

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	<b>AND</b>
	<b>Clinical criteria:</b>
New CC	The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea
	<b>AND</b>
	<b>Clinical criteria:</b>
New CC	The treatment must not be prescribed in combination with each of: a GLP-1 receptor agonist, insulin, another SGLT2 inhibitor
	<b>Prescribing Instructions:</b>
	Definition: A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
New P11	Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies: (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies), (b) Red cell transfusion within the previous 3 months. Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contra-indications in the patient's medical records.
7703	<b>Administrative Advice:</b> <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 AA1	<b>Administrative Advice:</b> Abbreviations used in the restriction are as follows: SGLT2 – sodium glucose transporter-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 (e.g., dulaglutide, semaglutide)  Where acarbose or pioglitazone are prescribed as part of therapy, the listed combinations in the restriction may also include these medicines.

**PBS-listings for Metformin combinations with Ertugliflozin**

On 1 January 2023, metformin combinations with ertugliflozin became Supply Only. These items can no longer be prescribed and will be de-listed from the PBS within 12 months. Therefore, the restrictions for these items will not be amended.

Category / Program: GENERAL – General Schedule (Code GE)					
MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№. of Rpts	Available brands
ERTUGLIFLOZIN + METFORMIN					
ertugliflozin 7.5 mg + metformin hydrochloride 500 mg tablet, 56	11562M MP 11568W MP NP	1	56	5	Segluromet 7.5/500
ertugliflozin 7.5 mg + metformin hydrochloride 1 g tablet, 56	11563N MP NP 11569X MP	1	56	5	Segluromet 7.5/1000
ertugliflozin 2.5 mg + metformin hydrochloride 1 g tablet, 56	11564P MP 11581M MP NP	1	56	5	Segluromet 2.5/1000
ertugliflozin 2.5 mg + metformin hydrochloride 500 mg tablet, 56	11575F MP NP 11584Q MP	1	56	5	Segluromet 2.5/500

**DPP4 inhibitors****PBS-listings for Linagliptin/Sitagliptin**

Category / Program: GENERAL – General Schedule (Code GE)					
MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
<b>LINAGLIPTIN</b>					
linagliptin 5 mg tablet, 30	11280Q MP 3387G MP NP	1	30	5	Trajenta
<b>SITAGLIPTIN</b>					
sitagliptin 25 mg tablet, 28	11572C MP 9180E MP NP	1	28	5	<sup>a</sup> Januvia <sup>a</sup> Sitagliptin Lupin (9180E only) <sup>a</sup> Sitagliptin SUN <sup>a</sup> Sitagliptin Sandoz Pharma <sup>a</sup> Xelevia
sitagliptin 50 mg tablet, 28	11573D MP 9181F MP NP	1	28	5	<sup>a</sup> Januvia <sup>a</sup> Sitagliptin Lupin (9181F only) <sup>a</sup> Sitagliptin SUN <sup>a</sup> Sitagliptin Sandoz Pharma <sup>a</sup> Xelevia
sitagliptin 100 mg tablet, 28	11576G MP 9182G MP NP	1	28	5	<sup>a</sup> Januvia <sup>a</sup> Sitagliptin Lupin (9182G only) <sup>a</sup> Sitagliptin SUN <sup>a</sup> Sitagliptin Sandoz Pharma <sup>a</sup> Xelevia
New restriction to replace:					
Authority Required (STREAMLINED) codes: 7541 (Initial tx. triple therapy with metformin + SGLT2), 7505 (Cont. tx triple therapy with metformin + SGLT2), 6346 (dual therapy with either metformin/sulfonylurea), 6363 (triple therapy with metformin & sulfonylurea), 6376 (in combination with insulin)					
<b>Restriction Summary [New] / ToC: [New]: Authority Required (STREAMLINED)</b>					
8995	<b>Indication:</b> Diabetes mellitus type 2				
	<b>Clinical criteria:</b>				
New CC	The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin.				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
New CC	The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
New CC	The treatment must not be prescribed in combination with each of: a GLP-1 receptor agonist, another DPP4 inhibitor.				
	<b>Prescribing Instructions:</b>				
	Definition: A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels				

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New PI1	<p>greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.</p> <p>Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:</p> <p>(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),</p> <p>(b) Red cell transfusion within the previous 3 months.</p> <p>Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contra-indications in the patient's medical records.</p>
7703	<p><b>Administrative Advice:</b> <b>Continuing Therapy Only:</b></p> <p>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.</p>
New AA1	<p><b>Administrative Advice:</b></p> <p>Abbreviations used in the restriction are as follows:</p> <p>SGLT2 – sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')</p> <p>DPP4 – dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')</p> <p>GLP-1 – glucagon-like peptide-1 receptor agonist (e.g., dulaglutide, semaglutide)</p> <p>Where acarbose or pioglitazone are prescribed as part of therapy, the listed combinations in the restriction may also include these medicines.</p>

**PBS-listings for Linagliptin/Sitagliptin in combination with metformin**

Category / Program: GENERAL – General Schedule (Code GE)					
MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
<b>LINAGLIPTIN + METFORMIN</b>					
linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60	10038H MP NP 11274J MP	1	60	5	Trajentamet
linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60	10044P MP NP 11282T MP	1	60	5	Trajentamet
linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60	10045Q MP NP 11294K MP	1	60	5	Trajentamet
<b>SITAGLIPTIN + METFORMIN</b>					
sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56	11582N MP 9450J MP NP	1	56	5	<sup>a</sup> Janumet <sup>a</sup> Sitagliptin/Metformin Sandoz <sup>a</sup> Velmetia
sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28	10089B MP NP 11566R MP	1	28	5	Janumet XR
sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56	10090C MP NP 11580L MP	1	56	5	Janumet XR
sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56	11574E MP 9451K MP NP	1	56	5	<sup>a</sup> Janumet <sup>a</sup> Sitagliptin/Metformin Sandoz <sup>a</sup> Velmetia

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sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56	11586T MP 9449H MP NP	1	56	5	<sup>a</sup> Janumet <sup>a</sup> Sitagliptin/Metformin Sandoz <sup>a</sup> Velmetia
New restriction to replace:  Linagliptin + metformin Authority Required (STREAMLINED) codes: 6333 (the FDC product alone), 6336 (Cont. tx of any regimen containing the 2 drugs), 6344 (triple therapy with a sulfonylurea), 6443 (in combination with insulin), 7507 (Initial tx of triple therapy of this FDC + SGLT2) 7530 (Cont. tx of triple therapy of this FDC + SGLT2)  Sitagliptin + metformin Authority Required (STREAMLINED) codes: 6333 (the FDC product alone), 6334 (Cont. tx of any regimen containing the 2 drugs), 6344 (triple therapy with a sulfonylurea), 6443 (in combination with insulin), 7507 (Initial tx of triple therapy of this FDC + SGLT2) 7530 (Cont. tx of triple therapy of this FDC + SGLT2)					
<b>Restriction Summary [New] / ToC: [New]: Authority Required (STREAMLINED)</b>					
8995	<b>Indication:</b> Diabetes mellitus type 2				
<b>Clinical criteria:</b>					
New CC	The condition must be inadequately responsive to metformin				
<b>AND</b>					
<b>Clinical criteria:</b>					
New CC	The treatment must not be prescribed in combination with each of: a GLP-1 receptor agonist, another DPP4 inhibitor				
New P11	<b>Prescribing Instructions:</b> Definition: A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.  Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies: (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies), (b) Red cell transfusion within the previous 3 months. Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contra-indications in the patient's medical records.				
7703	<b>Administrative Advice:</b> <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 AA1	<b>Administrative Advice:</b> Abbreviations used in the restriction are as follows: SGLT2 – sodium glucose transporter-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 (e.g., dulaglutide, semaglutide)				

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Where acarbose or pioglitazone are prescribed as part of therapy, the listed combinations in the restriction may also include these medicines.
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**PBS-listings for Alogliptin**

<b>Category / Program:</b> GENERAL – General Schedule (Code GE)					
<b>MEDICINAL PRODUCT medicinal product pack</b>	<b>PBS item code</b>	<b>Max. qty packs</b>	<b>Max. qty units</b>	<b>No. of Rpts</b>	<b>Available brands</b>
ALOGLIPTIN					
alogliptin 6.25 mg tablet, 28	2944Y MP NP	1	28	5	Nesina
alogliptin 12.5 mg tablet, 28	2933J MP NP	1	28	5	Nesina
alogliptin 25 mg tablet, 28	2986E MP NP	1	28	5	Nesina
New restriction to replace:  Authority Required (STREAMLINED) code(s): 4349 (dual therapy with either metformin/sulfonylurea)					
<b>Restriction Summary [New] / ToC: [New]: Authority Required (STREAMLINED)</b>					
8995	<b>Indication:</b> Diabetes mellitus type 2				
	<b>Clinical criteria:</b>				
New CC	The treatment must be dual combination therapy limited to this drug with either: metformin, a sulfonylurea.				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
New CC	The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
New CC	The treatment must not be prescribed in combination with each of: a GLP-1 receptor agonist, insulin, an SGLT2 inhibitor, another DPP4 inhibitor				
	<b>Prescribing Instructions:</b>				
	Definition: A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.				
New P11	Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies: (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies), (b) Red cell transfusion within the previous 3 months. Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contra-indications in the patient's medical records.				
	<b>Administrative Advice:</b>				
New AA1	Abbreviations used in the restriction are as follows: SGLT2 – sodium glucose transporter-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 (e.g., dulaglutide, semaglutide)				

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	Where acarbose or pioglitazone are prescribed as part of therapy, the listed combinations in the restriction may also include these medicines.
New AA2	<p><b>Administrative Advice:</b> SGLT2 inhibitors currently PBS-listed are: dapagliflozin, empagliflozin, ertugliflozin.</p> <p>Where an SGLT2 inhibitor is being accessed through another PBS-indication than diabetes, the clinical criteria in relation to not combining subsidy with an SGLT2 inhibitor does not apply (i.e., the PBS-indication of this listing is specifically in relation to diabetes mellitus type 2).</p>

**PBS-listings for Alogliptin + Metformin**

<b>Category / Program:</b> GENERAL – General Schedule (Code GE)					
MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ALOGLIPTIN + METFORMIN					
alogliptin 12.5 mg + metformin hydrochloride 1 g tablet, 56	10035E MP NP	1	56	5	Nesina Met 12.5/1000
alogliptin 12.5 mg + metformin hydrochloride 500 mg tablet, 56	10033C MP NP	1	56	5	Nesina Met 12.5/500
alogliptin 12.5 mg + metformin hydrochloride 850 mg tablet, 56	10032B MP NP	1	56	5	Nesina Met 12.5/850
New restriction to replace: Authority Required (STREAMLINED) codes: 4423 (the FDC product alone), 4427 (Cont. tx of any regimen containing the 2 drugs)					
<b>Restriction Summary [New] / ToC: [New]: Authority Required (STREAMLINED)</b>					
8995	<b>Indication:</b> Diabetes mellitus type 2				
	<b>Clinical criteria:</b>				
New CC3.2	The condition must be inadequately responsive to metformin				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
New TC	The treatment must not be prescribed in combination with each of: a GLP-1 receptor agonist, an SGLT2 inhibitor, insulin, another DPP4 inhibitor				
	<b>Prescribing Instructions:</b>				
	Definition: A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.				
New P11	Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies: (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies), (b) Red cell transfusion within the previous 3 months. Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contra-indications in the patient's medical records.				
7703	<b>Administrative Advice:</b> <b>Continuing Therapy Only:</b>				

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	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 AA1	<p><b>Administrative Advice:</b> Abbreviations used in the restriction are as follows: SGLT2 – sodium glucose transporter-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 (e.g., dulaglutide, semaglutide)</p> <p>Where acarbose or pioglitazone are prescribed as part of therapy, the listed combinations in the restriction may also include these medicines.</p>
New AA2	<p><b>Administrative Advice:</b> SGLT2 inhibitors currently PBS-listed are: dapagliflozin, empagliflozin, ertugliflozin.</p> <p>Where an SGLT2 inhibitor is being accessed through another PBS-indication than diabetes, the clinical criteria in relation to not combining subsidy with an SGLT2 inhibitor does not apply (i.e., the PBS-indication of this listing is specifically in relation to diabetes mellitus type 2).</p>

**PBS-listings for Saxagliptin**

<b>Category / Program:</b> GENERAL – General Schedule (Code GE)					
MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
SAXAGLIPTIN					
saxagliptin 5 mg tablet, 28	11311H MP 8983T MP NP	1	28	5	Onglyza
saxagliptin 2.5 mg tablet, 28	10128C MP NP 11292H MP	1	28	5	Onglyza
New restriction to replace:  Authority Required (STREAMLINED) codes: 7541 (Initial tx. triple therapy with metformin + SGLT2), 7505 (Cont. tx triple therapy with metformin + SGLT2), 6346 (dual therapy with either metformin/sulfonylurea), 6363 (triple therapy with metformin & sulfonylurea),					
<b>Restriction Summary [New] / ToC: [New]: Authority Required (STREAMLINED)</b>					
8995	<b>Indication:</b> Diabetes mellitus type 2				
	<b>Clinical criteria:</b>				
New CC1.8	The treatment must be used in combination with at least one of: metformin, a sulfonylurea				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
New CC3.1	The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
New CC	The treatment must not be prescribed in combination with each of: a GLP-1 receptor agonist, insulin, another DPP4 inhibitor				
	<b>Prescribing Instructions:</b> Definition: A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. This is inclusive of intolerances/contra-indications that require				

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New PI1	<p>permanent treatment discontinuation. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.</p> <p>Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:                  (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),                  (b) Red cell transfusion within the previous 3 months.</p> <p>Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contra-indications in the patient's medical records.</p>
7703	<p><b>Administrative Advice:</b>  <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.</p>
New AA1	<p><b>Administrative Advice:</b>                  Abbreviations used in the restriction are as follows:                  SGLT2 – sodium glucose transporter-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 (e.g., dulaglutide, semaglutide)</p> <p>Where acarbose or pioglitazone are prescribed as part of therapy, the listed combinations in the restriction may also include these medicines.</p>

**PBS-listings for Saxagliptin + Metformin**

<b>Category / Program:</b> GENERAL – General Schedule (Code GE)						
<b>MEDICINAL PRODUCT</b> <b>medicinal product pack</b>	<b>PBS item code</b>	<b>Max. qty packs</b>	<b>Max. qty units</b>	<b>No. of Rpts</b>	<b>Available brands</b>	
<b>SAXAGLIPTIN + METFORMIN</b>						
saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28	10055F MP NP 11312J MP	1	28	5	Kombiglyze XR 5/500	
saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28	10051B MP NP 11299Q MP	1	28	5	Kombiglyze XR 5/1000	
saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56	10048W MP NP 11285Y MP	1	56	5	Kombiglyze XR 2.5/1000	
<p>New restriction to replace:</p> <p>Authority Required (STREAMLINED) codes:                  6333 (the FDC product alone),                  6335 (Cont. tx of any regimen containing the 2 drugs),                  6344 (dual therapy with a sulfonylurea),                  7507 (Initial. tx triple therapy with this FDC product + SGLT2),                  7530 (Cont. tx triple therapy with this FDC product + SGLT2)</p>						
<b>Restriction Summary [New] / ToC: [New]: Authority Required (STREAMLINED)</b>						
8995	<b>Indication:</b> Diabetes mellitus type 2					
<b>Clinical criteria:</b>						

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New CC3.2	The condition must be inadequately responsive to metformin
	<b>AND</b>
	<b>Clinical criteria:</b>
New CC	The treatment must not be prescribed in combination with each of: a GLP-1 receptor agonist, insulin, another DPP4 inhibitor
New PI1	<p><b>Prescribing Instructions:</b>  Definition:  A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.</p> <p>Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:  (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),  (b) Red cell transfusion within the previous 3 months.</p> <p>Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contra-indications in the patient's medical records.</p>
7703	<p><b>Administrative Advice:</b>  <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.</p>
New AA1	<p><b>Administrative Advice:</b>  Abbreviations used in the restriction are as follows:  SGLT2 – sodium glucose transporter-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 (e.g., dulaglutide, semaglutide)</p> <p>Where acarbose or pioglitazone are prescribed as part of therapy, the listed combinations in the restriction may also include these medicines.</p>

**PBS-listings for Vildagliptin**

<b>Category / Program:</b> GENERAL – General Schedule (Code GE)					
<b>MEDICINAL PRODUCT</b>	<b>PBS item code</b>	<b>Max. qty packs</b>	<b>Max. qty units</b>	<b>No. of Rpts</b>	<b>Available brands</b>
<b>medicinal product pack</b>					
VILDAGLIPTIN					
vildagliptin 50 mg tablet, 60	3415R MP NP	1	60	5	Galvus
<p>New restriction to replace:</p> <p>Authority Required (STREAMLINED) codes:  6346 (dual therapy with either metformin/sulfonylurea),  6363 (triple therapy with metformin &amp; sulfonylurea),  6376 (in combination with insulin)</p>					
<b>Restriction Summary [New] / ToC: [New]: Authority Required (STREAMLINED)</b>					
8995	<b>Indication:</b> Diabetes mellitus type 2				
	<b>Clinical criteria:</b>				
New CC1.8	The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin.				

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	<b>AND</b>
	<b>Clinical criteria:</b>
New CC3.1	The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.
	<b>AND</b>
	<b>Clinical criteria:</b>
New CC	The treatment must not be prescribed in combination with each of: a GLP-1 receptor agonist, an SGLT2 inhibitor, another DPP4 inhibitor
New PI1	<p><b>Prescribing Instructions:</b>  Definition:  A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. This is inclusive of intolerances/contra-indications that require permanent treatment discontinuation. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.</p> <p>Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:  (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),  (b) Red cell transfusion within the previous 3 months.</p> <p>Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contra-indications in the patient's medical records.</p>
7703	<p><b>Administrative Advice:</b>  <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.</p>
New AA1	<p><b>Administrative Advice:</b>  Abbreviations used in the restriction are as follows:  SGLT2 – sodium glucose transporter-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 (e.g., dulaglutide, semaglutide)</p> <p>Where acarbose or pioglitazone are prescribed as part of therapy, the listed combinations in the restriction may also include these medicines.</p>
New AA2	<p><b>Administrative Advice:</b>  SGLT2 inhibitors currently PBS-listed are: dapagliflozin, empagliflozin, ertugliflozin.</p> <p>Where an SGLT2 inhibitor is being accessed through another PBS-indication than diabetes, the clinical criteria in relation to not combining subsidy with an SGLT2 inhibitor does not apply (i.e., the PBS-indication of this listing is specifically in relation to diabetes mellitus type 2).</p>

**PBS-listings for Vildagliptin + Metformin**

<b>Category / Program:</b> GENERAL – General Schedule (Code GE)					
<b>MEDICINAL PRODUCT</b> <b>medicinal product pack</b>	<b>PBS item code</b>	<b>Max. qty packs</b>	<b>Max. qty units</b>	<b>No. of Rpts</b>	<b>Available brands</b>
VILDAGLIPTIN + METFORMIN					
vildagliptin 50 mg + metformin hydrochloride 500 mg, 60	5474D MP NP	1	60	5	Galvumet 50/500
vildagliptin 50 mg + metformin hydrochloride 850 mg, 60	5475E MP NP	1	60	5	Galvumet 50/850

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vildagliptin 50 mg + metformin hydrochloride 1 g, 60	5476F MP NP	1	60	5	Galvumet 50/1000
New restriction to replace:					
Authority Required (STREAMLINED) codes: 6333 (this FDC product alone), 6357 (Cont. tx of any regimen containing the 2 drugs), 6344 (triple therapy with this FDC product + a sulfonylurea), 6443 (triple therapy with this FDC product + insulin)					
<b>Restriction Summary [New] / ToC: [New]: Authority Required (STREAMLINED)</b>					
8995	<b>Indication:</b> Diabetes mellitus type 2				
	<b>Clinical criteria:</b>				
New CC3.2	The condition must be inadequately responsive to metformin				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
New CC	The treatment must not be prescribed in combination with each of: a GLP-1 receptor agonist, an SGLT2 inhibitor, another DPP4 inhibitor				
	<b>Prescribing Instructions:</b>				
	Definition: A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.				
New PI1	Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies: (a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies), (b) Red cell transfusion within the previous 3 months.  Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contra-indications in the patient's medical records.				
	<b>Administrative Advice:</b>				
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>Administrative Advice:</b>				
New AA1	Abbreviations used in the restriction are as follows: SGLT2 – sodium glucose transporter-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 (e.g., dulaglutide, semaglutide)  Where acarbose or pioglitazone are prescribed as part of therapy, the listed combinations in the restriction may also include these medicines.				
	<b>Administrative Advice:</b>				
New AA2	SGLT2 inhibitors currently PBS-listed are: dapagliflozin, empagliflozin, ertugliflozin.  Where an SGLT2 inhibitor is being accessed through another PBS-indication than diabetes, the clinical criteria in relation to not combining subsidy with an SGLT2 inhibitor does not apply (i.e., the PBS-indication of this listing is specifically in relation to diabetes mellitus type 2).				

**GLP1 - RAs****Dulaglutide and Semaglutide**

<b>Category / Program:</b> GENERAL – General Schedule (Code GE)					
<b>MEDICINAL PRODUCT medicinal product pack</b>	<b>PBS item code</b>	<b>Max. qty packs</b>	<b>Max. qty units</b>	<b>№. of Rpts</b>	<b>Available brands</b>
DULAGLUTIDE					
dulaglutide 1.5 mg/0.5 mL injection, 4 x 0.5 mL pen devices	11364D MP NP	1	4	5	Trulicity
SEMAGLUTIDE					
semaglutide 1.34 mg/mL injection, 1 x 1.5 mL pen device	12080T MP NP	1	1	5	Ozempic
semaglutide 1.34 mg/mL injection, 1 x 3 mL pen device	12075M MP NP	1	1	5	Ozempic
<p>New restrictions to replace:</p> <p>Dulaglutide Authority Required (STREAMLINED) codes: 7645 (dual therapy with metformin), 5478 (triple therapy with metformin + a sulfonylurea), 5469 (combination therapy with insulin)</p> <p>Semaglutide Authority Required (STREAMLINED) codes: 5500 (dual therapy with either metformin/sulfonylurea), 5478 (triple therapy with metformin + a sulfonylurea), 5469 (combination therapy with insulin)</p>					
<b>Restriction Summary [New] / ToC: [New]: Authority Required</b> (telephone/electronic PBS authorities system)					
8995	<b>Indication:</b> Diabetes mellitus type 2				
	<b>Treatment Phase:</b> First PBS-prescription for this drug				
	<b>Clinical criteria:</b>				
	The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin.				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
	The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
	The patient must have a contraindication/intolerance requiring permanent treatment discontinuation to an SGLT2 inhibitor; OR				
	The condition must be inadequately responsive to treatment with an SGLT2 inhibitor.				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
	The treatment must not be prescribed in combination with each of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist				
25796	<b>Administrative Advice:</b> Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see <a href="http://www.servicesaustralia.gov.au/HPOS">www.servicesaustralia.gov.au/HPOS</a> ) or by telephone by contacting Services Australia on 1800 888 333.				
	<b>Administrative Advice:</b> Abbreviations used in the restriction are as follows:				

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New AA1	<p>SGLT2 – sodium glucose transporter-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 (e.g., dulaglutide, semaglutide)</p> <p>Where acarbose or pioglitazone are prescribed as part of therapy, the listed combinations in the restriction may also include these medicines.</p>
New AA2	<p><b>Administrative Advice:</b>  SGLT2 inhibitors currently PBS-listed are: dapagliflozin, empagliflozin, ertugliflozin.</p> <p>Where an SGLT2 inhibitor is being accessed through another PBS-indication than diabetes, the clinical criteria in relation to not combining subsidy with an SGLT2 inhibitor does not apply (i.e., the PBS-indication of this listing is specifically in relation to diabetes mellitus type 2).</p>
<b>Restriction Summary [New] / ToC: [New]: Authority Required (STREAMLINED)</b>	
8995	<b>Indication:</b> Diabetes mellitus type 2
	<b>Treatment Phase:</b> Subsequent PBS-prescriptions
	<b>Clinical criteria:</b>
	The treatment must not be prescribed in combination with each of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist
New AA1	<p><b>Administrative Advice:</b>  Abbreviations used in the restriction are as follows:  SGLT2 – sodium glucose transporter-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 (e.g., dulaglutide, semaglutide)</p> <p>Where acarbose or pioglitazone are prescribed as part of therapy, the listed combinations in the restriction may also include these medicines.</p>
New AA2	<p><b>Administrative Advice:</b>  SGLT2 inhibitors currently PBS-listed are: dapagliflozin, empagliflozin, ertugliflozin.</p> <p>Where an SGLT2 inhibitor is being accessed through another PBS-indication than diabetes, the clinical criteria in relation to not combining subsidy with an SGLT2 inhibitor does not apply (i.e., the PBS-indication of this listing is specifically in relation to diabetes mellitus type 2).</p>

**Pioglitazone**

Category / Program: GENERAL – General Schedule (Code GE)					
MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
PIOGLITAZONE					
Pioglitazone 15 mg tablet, 28	8694N MP NP	1	28	5	Multiple
Pioglitazone 30 mg tablet, 28	8695P MP NP	1	28	5	Multiple
Pioglitazone 45 mg tablet, 28	8696Q MP NP	1	28	5	Multiple
New restriction to replace Authority Required (STREAMLINED) codes: 4363 (dual therapy with metformin or sulfonylurea) 4388 (combination with insulin and oral therapies, or insulin alone where metformin is contraindicated) 4364 (triple therapy with metformin + sulfonylurea)					
<b>Restriction Summary [New] / ToC: [New]: Restricted Benefit</b>					
8995	<b>Indication:</b> Diabetes mellitus type 2				
7703	<b>Administrative Advice:</b> <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.				

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

## Appendix 2 – PBS Restrictions for T2DM Medicines Summary Table

The following tables provide an abridged description of the PBS subsidy rules for T2DM medicines.

Table A2.1. T2DM medicines with Unrestricted PBS listings, or Restricted Benefit for T2DM listings.

<b>Class</b>	<b>Drug</b>
<b><i>Biguanides</i></b>	Metformin
<b><i>Sulfonylureas</i></b>	Glibenclamide
	Gliclazide
	Glimepiride
	Glipizide
<b><i>Alpha glucosidase inhibitors</i></b>	Acarbose
<b><i>Insulins</i></b>	Insulins, except insulin detemir which is a Restricted Benefit for use in type 1 diabetes
<b><i>Thiazolidinediones</i></b>	Pioglitazone

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Table A2.2. Summary of PBS restrictions for Authority Required T2DM medicines.

Class	Drug (Brand name)	Dual therapy with met or SU	Triple therapy with met + SU	Dual/triple therapy with insulin (+/- met)	Triple therapy with met + SGLT2i	Triple therapy with met + DPP4i
<b>DPP4 inhibitors – ‘Gliptins’</b>	Alogliptin <sup>1</sup> (Nesina®)	✓	X	X	X	NA
	Linagliptin <sup>1,2</sup> (Trajenta®)	✓	✓	✓	✓	NA
	Saxagliptin <sup>1,2</sup> (Onglyza®)	✓	✓	X	✓	NA
	Sitagliptin <sup>1,2</sup> (multiple brands)	✓	✓	✓	✓	NA
	Vildagliptin <sup>1</sup> (Galvus®)	✓	✓	✓	X	NA
<b>SGLT2 inhibitors – ‘Flozins’</b>	Dapagliflozin <sup>1,3</sup> (Forxiga®)	✓	✓	✓	NA	✓
	Empagliflozin <sup>1,3</sup> (Jardiance®)	✓	✓	✓	NA	✓
	Ertugliflozin <sup>3</sup> (Steglatro®)	✓	X	X	NA	✓
<b>GLP-1 RAs</b>	Dulaglutide (Trulicity®)	✓ <sup>4</sup>	✓ <sup>4</sup>	✓ <sup>4</sup>	X	X
	Semaglutide (Ozempic®)	✓ <sup>4</sup>	✓ <sup>4</sup>	✓ <sup>4</sup>	X	X

Abbreviations: DPP4i = dipeptidyl-peptidase-4 inhibitor, Met = metformin, SGLT2i = sodium-glucose cotransporter 2 inhibitor, SU = sulfonylurea.

Key: Green = PBS-subsidised, Red = NOT PBS-subsidised, Orange = PBS-subsidised with contraindication/intolerance requirements.

Notes:

1. Fixed dose combination (FDC) products with metformin are available. FDCs are not subsidised for initial therapy.
2. FDC with SGLT2 inhibitor available. FDCs are not subsidised for initial therapy.
3. FDC with DPP4 inhibitor available. FDCs are not subsidised for initial therapy.
4. Patient must be contraindicated, intolerant, or inadequately responsive to an SGLT2 inhibitor (and the SGLT2 inhibitor treatment must cease). Telephone/electronic authority required for initiation.