

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

1 Purpose of Item

That the PBAC:

- 1.1 **Note** the comments received from prescriber groups on the proposed PBS restrictions changes for T2DM medicines.
- 1.2 **Note** the pre-PBAC responses received from sponsor companies.
- 1.3 **Recommend** any further changes to the PBS restrictions for pioglitazone, 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.

2 Background

- 2.1 At the March 2023 meeting, the PBAC made several recommendations regarding changes to the PBS restrictions for T2DM medicines, including:
 - 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.
 - 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.
 - That access to GLP-1 RAs in dual or triple therapy be limited to patients who have:
 - a contraindication or intolerance to an SGLT2 inhibitor requiring permanent treatment discontinuation; or
 - are inadequately responsive to treatment with an SGLT2 inhibitor, provided that the SGLT2 inhibitor was ceased.
 - That Administrative Advice be included to clarify that patients with chronic kidney disease (CKD) or chronic heart failure (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.
 - That pioglitazone could change to a Restricted Benefit listing for T2DM.
- 2.2 The PBAC further recommended that the Department of Health and Aged Care consult relevant consumer and prescriber groups on the proposed changes to the PBS restrictions for T2DM medicines, prior to final PBAC recommendation, to ensure that the restrictions were clear and concise.

Current PBS restrictions for T2DM medicines (abridged)

- 2.3 Metformin, sulfonylureas (SUs), acarbose and most insulins have unrestricted PBS listings. Insulin detemir has a restricted benefit listing for type 1 diabetes.
- 2.4 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.
- 2.5 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.
- 2.6 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 +
DPP4 inhibitors (Gliptins)	Alogliptin ²	✓	X	X	X
	Linagliptin ^{2,5}	✓	✓	✓ ³	SGLT2i
	Saxagliptin ^{2,5}	✓	✓	X	SGLT2i
	Sitagliptin ^{2,5}	✓	✓	✓ ³	SGLT2i
	Vildagliptin ²	✓	✓	✓ ³	X
SGLT2 inhibitors (Flozins)	Dapagliflozin ²	✓	✓	✓ ³	DPP4i
	Empagliflozin ^{2,4}	✓	✓	✓ ³	DPP4i
	Ertugliflozin ^{4,8}	✓	X	X	DPP4i
Thiazolidinediones (TZD)	Pioglitazone	✓ ¹	✓	✓ ³	X
GLP-1 RAs	Dulaglutide	✓ ^{1,6}	✓	✓ ⁷	X
	Semaglutide	✓ ¹	✓	✓ ⁷	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.

3 Current Situation

Stakeholder correspondence/engagement

- 3.1 The Department consulted the following organisations on the proposed PBS restriction changes for T2DM medicines recommended by the PBAC in March 2023:
- Australian Diabetes Society (ADS)
 - Royal Australian College of General Practitioners (RACGP) including the Diabetes Specific Interest Group
 - Diabetes Australia
 - Endocrine Society of Australia (ESA)
 - Australian Diabetes Educators Association (ADEA)
 - National Association of Diabetes Centres (NADC)
 - Australian College of Nursing (ACN) (diabetes education).
- 3.2 The Department specifically requested input on the following issues:
- Suggestions for making the restrictions clear and concise.
 - How to define 'inadequate response' to an SGLT2 inhibitor in the context of switching therapies to a GLP-1 RA.
 - Whether pioglitazone should change to a Restricted Benefit listing for T2DM.
 - Whether the PBS restrictions for DPP4 inhibitors should be aligned so that all DPP4 inhibitors are PBS-subsidised for use in triple therapy with metformin and a sulfonylurea, and in combination with SGLT2 inhibitors or insulin.
- 3.3 Four organisations provided responses.
- 3.4 Most stakeholders supported the proposed change in authority type for pioglitazone to a Restricted Benefit listing for T2DM. One stakeholder expressed concern that pioglitazone was not a first-line medicine for the treatment of T2DM.
- 3.5 Most stakeholders supported alignment of the PBS restrictions for DPP4 inhibitors, regarding use in combination with insulin, and use in triple therapy with metformin and an SGLT2 inhibitor. However, one stakeholder considered that in the absence of randomised controlled trial (RCT) evidence to support the use of specific DPP4 inhibitors with SGLT2 inhibitors or insulin, that the restrictions should remain.
- 3.6 Stakeholders considered it was important that the restrictions did not state that treatments could 'not be prescribed' in certain combinations, but that these combinations were 'not PBS-subsidised'.
- 3.7 Two stakeholders suggested removal of 'permanent' from the following clinical criterion for GLP-1 RAs: 'The patient must have a contraindication/intolerance requiring permanent treatment discontinuation to an SGLT2 inhibitor'. Stakeholders suggested that it would not be easy to define whether a contraindication or intolerance was likely to be permanent.

- 3.8 Stakeholders suggested the following clinical criteria for use in the proposed GLP-1 RA restriction, to define an 'inadequate response' to an SGLT2 inhibitor:
- The patient must have a documented inadequate response towards improved diabetes management goals with an SGLT2 inhibitor.
 - The patient must have a documented failure to improve clinical diabetes glycaemic goals with an SGLT2 inhibitor.
 - The patient must not have achieved a clinically meaningful response with an SGLT2 inhibitor.
- 3.9 One stakeholder considered that 'inadequate response' to an SGLT2 inhibitor may be difficult to define as the cardiovascular/heart failure benefits do not necessarily correlate with changes in HbA1c. This stakeholder suggested that if SGLT2 inhibitor treatment is clinically ineffective after 1-2 months, then swapping to another agent may be indicated.
- 3.10 One stakeholder considered that it should be made clearer that DPP4 inhibitor treatment should be ceased when commencing a GLP-1 RA. This stakeholder also considered that additional clarification that GLP-1 RAs and SGLT2 inhibitors were not subsidised for concomitant treatment was needed.
- 3.11 One stakeholder considered that the proposed restrictions for fixed dose combinations of SGLT2 inhibitor or DPP4 inhibitor with metformin seemed less restrictive than the proposed listings for SGLT2 inhibitors or DPP4 inhibitors alone.
- 3.12 Most stakeholders did not support the proposed change to the authority type for initiation of GLP-1 RA therapy. Stakeholders considered that the changes do not align with clinical guidelines, are contrary to personalised care, and will be onerous for prescribers.
- 3.13 One stakeholder claimed that the AWARD-10 study showed the significant benefit of the addition of dulaglutide to SGLT2 inhibitor treatment. The PBAC has not yet considered the cost-effectiveness of this combination through a PBAC submission.
- 3.14 One stakeholder suggested that the PBAC consider adapting the [Australian Type 2 Diabetes Glycaemic Management Algorithm](#) produced by the ADS when communicating changes to the restrictions with clinicians.

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

4 Sponsor comments

- 4.1 The sponsors of PBS-listed GLP-1 RAs, DPP4 inhibitors, SGLT2 inhibitors and pioglitazones were provided with an opportunity to provide a pre-PBAC response, in line with standard PBAC processes.
- 4.2 The sponsors of alogliptin, saxagliptin and vildagliptin were requested to provide any clinical trial data to support the use of these medicines in combinations not currently PBS-listed, including use in combination with insulin (with or without metformin) or SGLT2 inhibitors. The PBAC noted clinical trial data provided by one sponsor.
- 4.3 The PBAC noted the pre-PBAC comments from sponsors. Sponsors generally supported simplification of the PBS restrictions for T2DM medicines.

- 4.4 The PBAC noted that one sponsor considered that this work should have been undertaken as a Post-market Review.

5 PBAC Outcome

- 5.1 The PBAC noted that most stakeholders supported the change in the level of restriction for pioglitazone from Authority Required (Streamlined) to a Restricted Benefit listing. The PBAC considered that this change would provide an additional monotherapy option for patients who were contraindicated or intolerant to metformin. The PBAC noted that one stakeholder expressed concern about the potential for first-line use of pioglitazone. The PBAC considered that use of pioglitazone through the PBS was very low and that in the context of current clinical guidelines, first-line use of pioglitazone was unlikely to be an important clinical issue. Therefore, the PBAC considered that it was unnecessary to include a clinical criterion in the pioglitazone restriction requiring patients to be contraindicated or intolerant to metformin monotherapy. The PBAC re-affirmed its recommendation to change the authority type for pioglitazone listings to Restricted Benefit.
- 5.2 The PBAC noted stakeholder comments supporting alignment of the PBS restrictions for DPP4 inhibitors. The PBAC recommended that the DPP4 inhibitor restrictions be aligned, noting that under the revised restrictions this would primarily involve not specifically excluding the use of some DPP4 inhibitors (i.e., alogliptin, vildagliptin and saxagliptin) with insulin or SGLT2 inhibitors.
- 5.3 The PBAC re-affirmed its recommendation to remove the requirement for contraindication or intolerance to metformin for patients to use DPP4 inhibitors, SGLT2 inhibitors and GLP-1 RAs in dual therapy with insulin.
- 5.4 The PBAC re-affirmed its recommendation 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 should be via a streamlined authority.
- 5.5 Regarding the GLP-1 RA restrictions, the PBAC noted the comments from two stakeholders regarding the difficulty in ascertaining whether a contraindication or intolerance to an SGLT2 inhibitor was likely to be permanent. The PBAC recommended that the term 'permanent' should be removed from the revised PBS restrictions for GLP-1 RAs.
- 5.6 The PBAC noted that the revised restrictions specifically exclude the use of SGLT2 inhibitors in combination with GLP-1 RAs and considered that this sufficiently indicated that concomitant use was not PBS-subsidised. The PBAC noted that it had not yet assessed evidence supporting cost-effectiveness of this combination.
- 5.7 The PBAC considered that the stakeholder responses demonstrated the difficulty in defining 'inadequate response' to an SGLT2 inhibitor in the PBS restrictions for GLP-1 RAs. The PBAC noted that T2DM clinical guidelines generally recommend individualised HbA1c targets for patients and that the cardiovascular benefits of SGLT2 inhibitors may be independent of their glycaemic effects. The PBAC recommended that the restriction include the following text, 'The patient must not have achieved a clinically meaningful glycaemic response with an SGLT2 inhibitor', with the definition

of a clinically meaningful glycaemic response left open to prescriber discretion in the context of the individual patient.

- 5.8 The PBAC noted the suggestion from one sponsor to amend the following treatment criterion in the proposed GLP-1 RA restrictions to include the words ‘for type 2 diabetes mellitus’ (shown in bold): ‘The patient must not be undergoing concomitant PBS-subsidised treatment **for type 2 diabetes mellitus** with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist’. The PBAC agreed that this amendment was reasonable, noting that patients using an SGLT2 inhibitor for a non-diabetic indication, such as CHF or CKD, would still need to have failed to achieve a clinically meaningful glycaemic response to the SGLT2 inhibitor to qualify for subsidised GLP-1 RA treatment.
- 5.9 Taking account of the clinical need for a personalised approach to T2DM treatment, the PBAC considered that it may be appropriate to expand the PBS listings for GLP-1 RAs to include people with T2DM who have a body mass index (BMI) greater than 35 kg/m², for use in combination with metformin, sulfonylurea or insulin, and without a requirement for contraindication, intolerance or lack of a clinically meaningful glycaemic response to an SGLT2 inhibitor. The PBAC requested that the Department develop financial estimates of the cost of expanding GLP-1 RA use to this population for its consideration at a future meeting. The PBAC agreed that it would be appropriate to request GLP-1 RA sponsors to provide any data available to support expansion of these listings. The PBAC considered that the recommended changes to the GLP-1 RA restrictions could be implemented prior to consideration of the expanded listing.
- 5.10 The PBAC noted that responses from some stakeholders indicated that the current restrictions for T2DM medicines are confusing to prescribers as they are not explicit about combinations that are not subsidised. For example, one stakeholder indicated that the current PBS restrictions allowed the combination use of an SGLT2 inhibitor, with a DPP4 inhibitor and insulin. However, the cost-effectiveness of this combination has not been considered by the PBAC, and the current PBS restrictions were never intended to indicate that this combination was subsidised.
- 5.11 The PBAC noted the comment from one stakeholder that there should be a treatment criterion specifically precluding use of DPP4 inhibitors with GLP-1 RAs. The PBAC noted that, as previously recommended, the revised restrictions for T2DM medicines include a treatment criterion specifically excluding use with other treatments in combinations that are not PBS-subsidised. For example, in the recommended GLP-1 RA restrictions, the criterion is as follows: ‘The patient must not be undergoing concomitant PBS-subsidised treatment for type 2 diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist.’
- 5.12 The PBAC considered that it was important to clearly articulate that the PBS restrictions reflect the requirements for subsidisation and include consideration of the comparative cost-effectiveness of treatments in any educational materials developed to support the restriction changes. PBS restrictions are not intended to replace clinical treatment guidelines. The PBAC noted that the Department intends to seek clinical and professional design advice in the development of any materials used to communicate the PBS restrictions changes.

- 5.13 The PBAC noted that one stakeholder considered that the proposed restrictions for SGLT2 and DPP4 inhibitor fixed dose combinations (FDCs) with metformin seemed less restrictive than the single agent restrictions. The PBAC noted that this is because it is necessary to state that the single component products must be used in combination with metformin, a sulfonylurea or insulin, whereas for the FDCs, a criterion requiring use in combination with metformin is redundant. The PBAC considered that the apparent lower complexity of the FDC product restrictions may lead to increased prescribing of these products. The PBAC considered that T2DM therapy initiation with FDCs could be monitored in any future utilisation analyses and should be noted as a potential issue when developing educational materials.

Outcome:

Recommended

6 Recommended listings

- 6.1 Amend existing/recommended listing as follows:

List of Administrative Advice

The recommended PBS listings include Administrative Advice (AA) which is repeated across several of the restrictions. For simplicity, this text is shown here and only the corresponding code (e.g., new AA1) is included in the restrictions below.

Administrative Advice

Concept ID	Text
7703	Administrative Advice: Continuing Therapy Only: 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	Administrative Advice: 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
New AA2	Administrative Advice: Where an SGLT2 inhibitor is being accessed through a PBS indication other than diabetes, the clinical criterion excluding concomitant treatment with an SGLT2 inhibitor is in relation to diabetes mellitus type 2 only.
New AA3	Administrative Advice: 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.

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Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contra-indications in the patient's medical records.

SGLT2 inhibitors

Delete 1 item code per product.

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
DAPAGLIFLOZIN					
dapagliflozin 10 mg tablet, 28	10011X MP NP 11291G MP	1	28	5	Forxiga
EMPAGLIFLOZIN					
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)					
Restriction Summary [New 1] / ToC: [New 1.1]: Authority Required (STREAMLINED)					
8995	Indication: Diabetes mellitus type 2				
New CC1	Clinical criteria:				
New CC1.1	The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin.				
	AND				
New CC2	Clinical criteria:				
New CC2.1	The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.				
New TC1	Treatment criteria:				
New TC1.1	The patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.				
	Administrative Advice				
New AA3	Refer to List above				
7703	Refer to List above				
New AA1	Refer to List above				

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Dapagliflozin/empagliflozin and metformin combinations

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
DAPAGLIFLOZIN + METFORMIN					
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
EMPAGLIFLOZIN + METFORMIN					
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 MP	1	60	5	Jardiamet 12.5 mg/1000 mg
<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>					
Restriction Summary [New 2] / ToC: [New 2.1]: Authority Required (STREAMLINED)					
8995	Indication: Diabetes mellitus type 2				
New CC3	Clinical criteria:				
New CC3.1	The condition must be inadequately responsive to metformin				
New TC1	Treatment criteria:				

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New TC1.1	The patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.
	Administrative Advice
New AA3	Refer to List above
7703	Refer to List above
New AA1	Refer to List above

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	No. of Rpts	Available brands
SAXAGLIPTIN + DAPAGLILOZIN					
saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28	11286B MP 11305B MP NP	1	28	5	Qtern 5/10
EMPAGLILOZIN + LINAGLIPTIN					
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
New restriction to replace: Authority Required (STREAMLINED) codes: 7524 (Initial tx with this FDC product + metformin), 7556 (Cont. tx with this FDC product + metformin)					
Restriction Summary [New 3] / ToC: [New 3.1]: Authority Required (STREAMLINED)					
8995	Indication: Diabetes mellitus type 2				
New CC4	Clinical criteria:				
New CC4.1	The treatment must be in combination with at least metformin				
	AND				
New CC5	Clinical criteria:				
New CC5.1	The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DDP-4 inhibitor, an SGLT2 inhibitor				
New TC2	Treatment criteria:				
New TC2.1	The patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, insulin, another SGLT2 inhibitor, another DPP4 inhibitor				
	Administrative Advice				
New AA3	Refer to List above				
7703	Refer to List above				
New AA1	Refer to List above				

DPP4 inhibitors

Delete 1 item code per product (except vildagliptin).

Linagliptin/Sitagliptin/Alogliptin/Saxagliptin/Vildagliptin

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
LINAGLIPTIN					
linagliptin 5 mg tablet, 30	11280Q MP 3387G MP NP	1	30	5	Trajenta
SITAGLIPTIN					
sitagliptin 25 mg tablet, 28	11572C MP 9180E MP NP	1	28	5	^a Januvia ^a Sitagliptin Lupin (9180E only) ^a Sitagliptin SUN ^a Sitagliptin Sandoz Pharma ^a Xelevia
sitagliptin 50 mg tablet, 28	11573D MP 9181F MP NP	1	28	5	^a Januvia ^a Sitagliptin Lupin (9181F only) ^a Sitagliptin SUN ^a Sitagliptin Sandoz Pharma ^a Xelevia
sitagliptin 100 mg tablet, 28	11576G MP 9182G MP NP	1	28	5	^a Januvia ^a Sitagliptin Lupin (9182G only) ^a Sitagliptin SUN ^a Sitagliptin Sandoz Pharma ^a Xelevia
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
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
VILDAGLIPTIN					
vildagliptin 50 mg tablet, 60	3415R MP NP	1	60	5	Galvus
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) 4349 (dual therapy with either metformin/sulfonylurea)					
Restriction Summary [New 4] / ToC: [New 4.1]: Authority Required (STREAMLINED)					

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8995	Indication: Diabetes mellitus type 2
New CC1	Clinical criteria:
New CC1.1	The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin.
	AND
New CC2	Clinical criteria:
New CC2.1	The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.
New TC3	Treatment criteria:
New TC3.1	The patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.
	Administrative Advice
New AA3	Refer to List above
7703	Refer to List above
New AA1	Refer to List above

Linagliptin/Sitagliptin/Alogliptin/Saxagliptin/Vildagliptin 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
LINAGLIPTIN + METFORMIN					
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
SITAGLIPTIN + METFORMIN					
sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56	11582N MP 9450J MP NP	1	56	5	^a Janumet ^a Sitagliptin/Metformin Sandoz ^a 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	^a Janumet ^a Sitagliptin/Metformin Sandoz ^a Velmetia
sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56	11586T MP 9449H MP NP	1	56	5	^a Janumet ^a Sitagliptin/Metformin Sandoz ^a Velmetia

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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
SAXAGLIPTIN + METFORMIN					
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
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
vildagliptin 50 mg + metformin hydrochloride 1 g, 60	5476F MP NP	1	60	5	Galvumet 50/1000
New restriction to replace:					
<p>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) 6334 (Cont. tx of any regimen containing the 2 drugs) 4423 (the FDC product alone) 4427 (Cont. tx of any regimen containing the 2 drugs) 6335 (Cont. tx of any regimen containing the 2 drugs), 6357 (Cont. tx of any regimen containing the 2 drugs)</p>					
Restriction Summary [New 5] / ToC: [New 5.1]: Authority Required (STREAMLINED)					
8995	Indication: Diabetes mellitus type 2				
New CC3	Clinical criteria:				
New CC3.1	The condition must be inadequately responsive to metformin				
New TC3	Treatment criteria:				
New TC3.1	The patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor				
	Administrative Advice				
New AA3	Refer to List above				
7703	Refer to List above				
New AA1	Refer to List above				

GLP1 RAs**Dulaglutide and Semaglutide**

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
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
New restrictions to replace:					
Dulaglutide Authority Required (STREAMLINED) codes: 7645 (dual therapy with metformin), 5478 (triple therapy with metformin + a sulfonylurea), 5469 (combination therapy with insulin)					
Semaglutide Authority Required (STREAMLINED) codes: 5500 (dual therapy with either metformin/sulfonylurea), 5478 (triple therapy with metformin + a sulfonylurea), 5469 (combination therapy with insulin)					
Restriction Summary [New 6] / ToC: [New 6.1]: Authority Required					
8995	Indication: Diabetes mellitus type 2				
	Treatment Phase: First PBS-prescription for this drug				
New CC1	Clinical criteria:				
New CC1.1	The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin.				
	AND				
New CC2	Clinical criteria:				
New CC2.1	The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.				
	AND				
New CC6	Clinical criteria:				
New CC6.1	The patient must not have achieved a clinically meaningful glycaemic response with an SGLT2 inhibitor; or				
New CC6.2	The patient must have a contraindication/intolerance requiring treatment discontinuation of an SGLT2 inhibitor				
New TC4	Treatment criteria:				
New TC4.1	The patient must not be undergoing concomitant PBS-subsidised treatment for type 2 diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist				
	Administrative Advice				
New AA3	Refer to List above				
New AA1	Refer to List above				
New AA2	Refer to List above				
	Administrative Advice:				
25796					

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	Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
Restriction Summary [New] / ToC: [New]: Authority Required (STREAMLINED)	
8995	Indication: Diabetes mellitus type 2
	Treatment Phase: Subsequent PBS-prescriptions for any GLP-1 receptor agonist
New TC4	Treatment criteria:
New TC4.1	The patient must not be undergoing concomitant PBS-subsidised treatment for type 2 diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist
	Administrative Advice
New AA1	Refer to List above
New AA2	Refer to List above

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	^a APOTEX-Pioglitazone ^a Acpio 15 ^a Actaze ^a Actos ^a Vexazone
pioglitazone 30 mg tablet, 28	8695P MP NP	1	28	5	^a APOTEX-Pioglitazone ^a Acpio 30 ^a Actaze ^a Actos ^a NOUMED PIOGLITAZONE ^a Pioglitazone Sandoz ^a Vexazone
pioglitazone 45 mg tablet, 28	8696Q MP NP	1	28	5	^a APOTEX-Pioglitazone ^a Acpio 45 ^a Actaze ^a Actos ^a NOUMED PIOGLITAZONE ^a Pioglitazone Sandoz ^a Vexazone
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)					
Restriction Summary [New] / ToC: [New]: Restricted Benefit					
8995	Indication: Diabetes mellitus type 2				
	Administrative Advice				
7703	Refer to List above				

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