

6.06 EMPAGLIFLOZIN

oral film coated tablets, 10 mg and 25 mg, Jardiance[®], Boehringer Ingelheim

1 Purpose of Application

- 1.1 The submission requested an extension to the current empagliflozin PBS listing for type 2 diabetes to include an Authority Required (Streamlined) listing for empagliflozin 10mg and 25mg in combination with metformin and a sulfonylurea (triple oral therapy) when combination therapy with both agents does not provide adequate glycaemic control.

2 Requested listing

Suggestions and additions proposed by the Secretariat to the requested listing are added in italics and suggested deletions are crossed out with strikethrough.

| Name, Restriction, Manner of administration and form | Max. Qty | No. of Rpts | Dispensed Price for Max. Qty | Proprietary Name and Manufacturer |
|--|----------|-------------|------------------------------|---------------------------------------|
| EMPAGLIFLOZIN Film coated tablet, 10mg | 30 | 5 | \$60.97 | Jardiance® Boehringer Ingelheim |
| EMPAGLIFLOZIN Film coated tablet, 25mg | 30 | 5 | \$60.97 | |

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| Category / Program | GENERAL – General Schedule (Code GE) |
| Prescriber type: | <input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives |
| Condition: | Diabetes mellitus type 2 |
| PBS Indication: | Diabetes mellitus type 2 |
| Restriction Level / Method: | <input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input checked="" type="checkbox"/> Streamlined |

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| <p>Clinical criteria:</p> | <p>The treatment must be in combination with metformin, AND</p> <p>The treatment must be in combination with a sulfonylurea, AND</p> <p>Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea <i>optimal doses of dual oral therapy</i>;</p> <p>OR</p> <p>Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea <i>optimal doses of dual oral therapy</i>.</p> <p>The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:</p> <p>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</p> <p>(b) Had red cell transfusion within the previous 3 months</p> <p>The result of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.</p> |
| <p>Prescriber Instructions</p> | <p>The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.</p> <p>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.</p> <p>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:</p> <p>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</p> <p>(b) Had red cell transfusion within the previous 3 months</p> <p>The result of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.</p> |

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| Administrative Advice | Note: 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. Note: This drug is not PBS subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1. <i>PBS subsidised dual oral therapy does not include concomitant use of two of either: a gliptin, a glitazone or an SGLT2 inhibitor.</i> |
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- 2.1 The listing was requested on a cost-minimisation basis compared to dapagliflozin.

For more detail on PBAC's view, see section 7 "PBAC outcome"

3 Background

- 3.1 **TGA status at time of PBAC meeting:** Empagliflozin 10mg and 25mg were TGA registered on 30 April 2014 for the treatment of type 2 diabetes to improve glycaemic control in adults as: monotherapy in patients who are intolerant to metformin; add-on combination therapy with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.
- 3.2 The starting dose for empagliflozin is 10mg daily. In patients tolerating empagliflozin 10mg and requiring additional glycaemic control, the dose can be increased to 25mg daily.
- 3.3 Empagliflozin has not previously been considered by PBAC for triple oral therapy in type 2 diabetes.
- 3.4 Empagliflozin 10mg and 25mg is currently PBS-listed for dual therapy in combination with metformin or a sulfonylurea.
- 3.5 There were two concurrent submissions for empagliflozin in type 2 diabetes: empagliflozin in combination with insulin; and empagliflozin plus metformin fixed dose combinations.

For more detail on PBAC's view, see section 7 "PBAC outcome"

4 Clinical place for the proposed therapy

- 4.1 Type 2 diabetes as triple therapy in combination with metformin and a sulfonylurea when treatment with both agents does not provide adequate glycaemic control. Alternative agents for triple therapy in combination with metformin and a sulfonylurea include dapagliflozin, pioglitazone, DPP-4 inhibitors, glucagon-like peptide 1 (GLP-1) receptor agonists and insulin.
- 4.2 Dapagliflozin was PBS listed for triple therapy combination with metformin and a sulfonylurea on 1 July 2015.

For more detail on PBAC's view, see section 7 "PBAC outcome"

5 Comparator

- 5.1 The submission nominated dapagliflozin, currently PBS listed for use in combination with metformin and a sulfonylurea, as the main comparator.
- 5.2 The PBAC considered that this was appropriate.

For more detail on PBAC's view, see section 7 "PBAC outcome"

6 PBAC consideration of the evidence

Sponsor hearing

- 6.1 There was no hearing for this item.

Consumer comments

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

Clinical trials

- 6.3 The submission was based on an indirect comparison of empagliflozin 10mg and 25mg (Trial 1245.23) with dapagliflozin 10mg (Study 05), in combination with metformin and a sulfonylurea, with placebo in combination with metformin and a sulfonylurea as the common comparator.
- 6.4 The submission also presented two indirect comparisons as supportive analyses:
- empagliflozin 10mg and 25mg (Trial 1245.23) vs the meta-analysed results of three dapagliflozin studies (Study 05 and two post-hoc subgroup analyses Study 18 and Study 19).
 - empagliflozin 10mg and 25mg (Extension Study 1245.31) vs dapagliflozin (Study 05 extension) based on results from extension studies.

The post-hoc subgroup analyses used in the indirect comparison were excluded from the evaluation. Neither results nor background characteristics of the trial populations

were presented in the published studies. Similarly, both studies were excluded from the March 2015 submission for dapagliflozin in triple therapy.

6.5 Details of the trials presented in the submission are provided in the Table 1.

Table 1 Trials and associated reports presented in the submission

| Trial ID | Protocol title/ Publication title | Publication citation |
|--|---|---|
| Empagliflozin 10mg vs empagliflozin 25mg vs placebo, all in combination with metformin and a sulfonylurea | | |
| Trial 1245.23 NCT01159600 | A phase III randomised, double-blind, placebo-controlled, parallel group, efficacy and safety study of BI 10773 (10 mg, 25 mg) administered orally, once daily over 24 weeks in patients with type 2 diabetes mellitus with insufficient glycaemic control despite treatment with metformin alone or metformin in combination with a sulfonylurea. Doc. No.: U12-1518-01 | Internal Study Report September 2012 |
| | Haring HU, Merker L, Seewaldt-Becker E, Weimer M, Meinicke T, Woerle HJ et al. Empagliflozin as add-on to metformin plus sulfonylurea in patients with type 2 diabetes: a 24-week, randomized, double-blind, placebo-controlled trial. | Diabetes Care 2013a; 36(11):3396-404. |
| Extension Study 1245.31 (extension of 1245.19, 1245.20 and 1245.23) NCT01289990 | A phase III double-blind, extension, placebo-controlled parallel group safety and efficacy trial of BI 10773 (10 and 25 mg once daily) and sitagliptin (100 mg once daily) given for minimum 76 weeks (including 24 weeks of preceding trial) as monotherapy or with different background therapies in patients with type 2 diabetes mellitus previously completing trial 1245.19, 1245.20 or 1245.23. Doc. No.: c02155992-02 | Internal study report May 2014 |
| Dapagliflozin 10mg vs placebo, both in combination with metformin and a sulfonylurea | | |
| Study 05 NCT01392677 | Matthaei S, Bowering K, Rohwedder K, Grohl A, Parikh S, Study 05 Group. Dapagliflozin Improves Glycemic Control and Reduces Body Weight as Add-on Therapy to Metformin Plus Sulfonylurea: A 24-Week Randomized, Double-Blind Clinical Trial. | Diabetes Care 2015; 38(3):365-72. |
| Study 18 NCT01031680 | Jabbour S, Hardy E, De Bruin TW, Gause-Nilsson I, Rohwedder K, Martin P et al. Dapagliflozin helps reduce HbA1c and body weight in patients with type 2 diabetes as part of triple combination therapy: A subanalysis of four clinical studies. | Diabetologia Conference: 49th Annual Meeting of the European Association for the Study of Diabetes, EASD 2013 Barcelona Conference Publication; September 2013a; 56(pp S375). |
| | Jabbour S, Hardy E, Debruin TW, Gause-Nilsson I, Rohwedder K, Martin P et al. Dapagliflozin as part of triple combination therapy helps reduce HbA1c and body weight in patients with type 2 diabetes. | Diabetes Conference: 73rd Scientific Sessions of the American Diabetes Association Chicago, IL United States Conference Publication; July 2013b; 62(pp A306-A307) |
| | Cefalu WT, Leiter LA, de Bruin TW, Gause-Nilsson I4, Sugg J, Parikh SJ. Dapagliflozin's Effects on Glycemia and Cardiovascular Risk Factors in High-Risk Patients With Type 2 Diabetes: A 24-Week, Multicenter, | Diabetes Care. 2015 pii: dc140315. |

| Trial ID | Protocol title/ Publication title | Publication citation |
|-------------------------|---|--|
| | Randomized, Double-Blind, Placebo-Controlled Study With a 28-Week Extension. | |
| Study 19 NCT01042977 | Jabbour S, Hardy E, De Bruin TW, Gause-Nilsson I, Rohwedder K, Martin P et al. Dapagliflozin helps reduce HbA1c and body weight in patients with type 2 diabetes as part of triple combination therapy: A subanalysis of four clinical studies. | Diabetologia Conference: 49th Annual Meeting of the European Association for the Study of Diabetes, EASD 2013 Barcelona Conference Publication; September 2013a; 56(pp S375) |
| | Jabbour S, Hardy E, Debruin TW, Gause-Nilsson I, Rohwedder K, Martin P et al. Dapagliflozin as part of triple combination therapy helps reduce HbA1c and body weight in patients with type 2 diabetes. | Diabetes Conference: 73rd Scientific Sessions of the American Diabetes Association Chicago, IL United States Conference Publication; July 2013b; 62(pp A306-A307) |
| | Leiter LA, Cefalu WT, de Bruin TW, Gause-Nilsson I, Sugg J, Parikh SJ. Dapagliflozin added to usual care in individuals with type 2 diabetes mellitus with preexisting cardiovascular disease: a 24-week, multicenter, randomized, double-blind, placebo-controlled study with a 28-week extension. | Journal of the American Geriatrics Society 2014; 62(7):1252-1262 |

Source: Tables B.5 and B.6 of the submission

6.6 The key features of the randomised trials are summarised in Table 2.

Table 2 : Key features of the included evidence

| Trial | N | Design | Comparison | Background diabetes medicines | Patient population | Risk of bias |
|--|---|---------------------------------------|--|---|---------------------|--------------|
| Empagliflozin 10mg vs empagliflozin 25mg vs placebo (metformin + sulfonylurea background) | | | | | | |
| Trial 1245.23^a (24 weeks) | 669 | RCT double-blinded multi centre | EMPA 10mg+MET+SU vs EMPA 25mg+MET+SU vs PBO+MET+SU | Metformin ≥1500mg/day + SU at max tolerated dose (≥50% of max dose) | HbA1c 7.0- 10.0% | Low |
| Extension Study 1245.31^a (52 week extension) ^b | 474 | Double-blinded multi centre extension | EMPA 10mg+MET+SU vs EMPA 25mg+MET+SU vs PBO+MET+SU | Metformin ≥1500mg/day + SU at max tolerated dose (≥50% of max dose) | HbA1c 7.0- 10.0% | High |
| Dapagliflozin 10mg vs placebo (metformin + sulfonylurea background) | | | | | | |
| Study 05 (24 weeks) | 218 | RCT double-blinded multi centre | DAPA 10mg+MET+SU vs PBO+MET+SU | Metformin ≥1500mg/day + SU at max tolerated dose (≥50% of max dose) | HbA1c 7.0- 10.5% | Low |
| Study 05 extension (28 week extension) | Limited information was identified for the Study 05 extension. Data presented were abstracts from conference presentations. | | | | | Unclear |

^aOnly empagliflozin triple therapy substudies were included in analyses

^bExtension Study 1245.31 consisted of three substudies of patients who completed Trial 1245.19, 1245.20 and 1245.23

Abbreviations: DAPA=dapagliflozin; EMPA=empagliflozin; HbA1c=glycated haemoglobin; max=maximum; MET=metformin; RCT=randomised controlled trial; SU=sulfonylurea.

Source: compiled during the evaluation.

6.7 Only the pre-specified empagliflozin triple therapy substudies from Trial 1245.23 and extension Study 1245.31 were analysed in the submission. All further references to

Trial 1245.23 and extension Study 1245.31 refer to the empagliflozin triple therapy substudy arms of these studies.

- 6.8 Overall, the risk of bias for the trials used in the main indirect comparison (Trial 1245.23 and Study 05) was low. However, the risk of bias was high for the extension studies used in the supportive analyses. This was due to the substantial proportion of patients not entering Extension Study 1245.31 from the initial Trial 1245.23 and the limited data available for the Study 05 extension.

Comparative effectiveness

6.9 Table 3 : Mean change in HbA1c from baseline to endpoint, indirect comparison between treatments

| Trial ID | LS mean change from baseline HbA1c (SD) | | | Adjusted mean difference (95% CI) ^a |
|---|---|--------------|--------------------|--|
| | Empagliflozin 10mg | Placebo | Dapagliflozin 10mg | |
| Empagliflozin 10mg vs dapagliflozin 10mg, Week 24 | | | | |
| Trial 1245.23 (24 weeks) | -0.82 (0.75) | -0.17 (0.75) | - | -0.64 (-0.78, -0.50) |
| Study 05 (24 weeks) | - | -0.17 (0.73) | -0.86 (0.73) | -0.69 (-0.89, -0.49) |
| Indirect comparison empagliflozin 10mg vs dapagliflozin 10mg, Week 24 | | | | |
| Empagliflozin 25mg vs dapagliflozin 10mg, Week 24 | | | | |
| | Empagliflozin 25mg | Placebo | Dapagliflozin 10mg | |
| Trial 1245.23 (24 weeks) | -0.77 (0.73) | -0.17 (0.75) | - | -0.59 (-0.73, -0.45) |
| Study 05 (24 weeks) | - | -0.17 (0.73) | -0.86 (0.73) | -0.69 (-0.89, -0.49) |
| Indirect comparison empagliflozin 25mg vs dapagliflozin 10mg, Week 24 | | | | |

^a Adjusted mean presented. ANCOVA model included treatment, renal function, region, and baseline HbA1c

Abbreviations: CI=confidence interval; LS=least squares; SD=standard deviation

Source: Table B.28 p117 of the submission

- 6.10 Individual trial results suggested that empagliflozin 10mg resulted in a slightly larger reduction in HbA1c compared with empagliflozin 25mg. A dose-response relationship for empagliflozin is established in other indications but not for the requested listing in triple therapy (TGA clinical evaluation report).
- 6.11 The results of the indirect analyses were consistent with no statistically significant differences between empagliflozin and dapagliflozin in reduction in HbA1c at 24 weeks. Non-inferiority was demonstrated with the upper limit of the 95% confidence intervals not exceeding the MCID of 0.4%, which was previously accepted by PBAC (March 2015 Dapagliflozin PSD).

Comparative harms

- 6.12 Compared to placebo, both empagliflozin and dapagliflozin were associated with higher rates of hypoglycaemia, urinary tract infections and genital infections. Generally, the hypoglycaemia events did not require either non-medical or medical assistance. Similar proportions of patients experienced adverse events in the empagliflozin 10mg and 25mg arms.
- 6.13 A TGA communication released on 13 August 2015 warned that use of SGLT2 inhibitors, empagliflozin, dapagliflozin and canagliflozin may lead to ketoacidosis (see discussion in Section B.7 of the commentary).

Clinical claim

- 6.14 The submission described empagliflozin 10mg and 25mg as non-inferior in terms of comparative effectiveness and similar in terms of comparative safety over dapagliflozin 10mg, when used in combination with metformin and a sulfonylurea in the treatment of type 2 diabetes mellitus.
- 6.15 The PBAC considered that the clinical claim was adequately supported.
- 6.16 The PBAC recalled that it had previously accepted non-inferiority between empagliflozin and dapagliflozin in terms of comparative safety in dual oral therapy (July 2014 empagliflozin PSD).

Economic analysis

- 6.17 Cost-minimisation analysis. The equi-effective doses in the submission were:
Empagliflozin 10mg or 25mg = dapagliflozin 10mg

These estimates were based on the indirect analysis comparing empagliflozin and dapagliflozin. The PBAC has previously considered that empagliflozin 25mg is equi-effective to dapagliflozin 10mg [July 2014 Empagliflozin (dual therapy) PSD].

- 6.18 The submission proposed a flat pricing structure for empagliflozin 10mg and 25mg, based on the listed price of dapagliflozin 10mg and similar to the listing for empagliflozin 10mg and 25mg in dual therapy (as at 1 July 2015).

Drug cost/patient/year: \$742

- 6.19 At the requested DPMQ of \$60.97 for a 30 pack of empagliflozin 10mg or 25mg, the drug cost per patient per year for empagliflozin was estimated to be \$742 (assuming 12.17 packs per year). The DPMQ for dapagliflozin 10mg is \$57.60 for a 28 pack, with a drug cost per patient per year of \$750 (assuming 13.04 packs per year).

Estimated PBS usage & financial implications

- 6.20 This submission was not considered by DUSC. The submission presented a market share approach, with estimates based on extrapolated trends of use in triple therapy derived from an analysis of the 10% Medicare sample. The submission also assumed the likely uptake of sodium glucose transporter-2 (SGLT2) inhibitors of the total triple therapy market and substitution patterns.

Table 4 : Estimated use and financial implications

| | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
|--|---------------------|-----------|-----------|-----------|-----------|
| Estimated extent of use | | | | | |
| Total number of SGLT2 inhibitor scripts (without empagliflozin) | ██████ | ██████ | ██████ | ██████ | ██████ |
| Total number of SGLT2 inhibitor scripts (with empagliflozin) ^a | ██████ | ██████ | ██████ | ██████ | ██████ |
| Empagliflozin market uptake from SGLT2 inhibitors | ██████ ^b | ██████ | ██████ | ██████ | ██████ |
| - Empagliflozin 10mg (56% of total empagliflozin utilisation) ^c | ██████ | ██████ | ██████ | ██████ | ██████ |
| - Empagliflozin 25mg (44% of total empagliflozin utilisation) ^c | ██████ | ██████ | ██████ | ██████ | ██████ |
| Total empagliflozin scripts | ██████ | ██████ | ██████ | ██████ | ██████ |
| Estimated net cost to PBS/RPBS (less patient co-payments) | | | | | |
| Total cost of SGLT2 inhibitor market (without empagliflozin) | \$ ██████ | \$ ██████ | \$ ██████ | \$ ██████ | \$ ██████ |
| Total cost of SGLT2 inhibitor market (with empagliflozin) | \$ ██████ | \$ ██████ | \$ ██████ | \$ ██████ | \$ ██████ |
| Net cost | \$ ██████ | \$ ██████ | \$ ██████ | \$ ██████ | \$ ██████ |

^aNumber of prescriptions when empagliflozin is included in triple therapy market is slightly less due to larger pack size (30 pack) vs dapagliflozin (28 pack)

^bIn Year 1, market share of empagliflozin increases by approximately █% per month starting at █% at 1 April 2016 increasing to █% by 30 March 2017

^cAssumption by sponsor

Abbreviations: SGLT2=sodium-glucose cotransporter 2

Source: Tables E.2-1 to E.2-4, E.3-1 to E.3-4, and E.4-1 of the submission

The redacted table above shows that the number scripts for empagliflozin is estimated to be 10,000 – 50,000 in Year 1 and 50,000 – 100,000 in Year 5. The estimated net cost to the PBS is less than \$10 million per year.

- 6.21 The submission estimated that the listing of empagliflozin in triple therapy combination will result in a small additional cost to the PBS. The estimate may not be reliable given the following issues:
- The 10% Medicare sample analysis used to estimate the total triple market therapy was not provided and could not be verified. *The Pre-Sub-Committee Response (PSCR) (p1-2) reiterated the methodology used for this analysis.*
 - The linear projection for growth in the triple therapy market was based on data obtained prior to PBS listing of dapagliflozin in triple therapy. The extrapolation was implausible given the data presented assumed no growth in patient numbers from November 2014 to April 2016. *The PSCR (p2) explained that ‘substantial growth has been assumed to occur in the total triple therapy market over the analysis period’.*
 - Empagliflozin may increase the triple oral therapy market in type 2 diabetes, as it offers dose titration and has slightly different characteristics (in precautions and contraindications as per product information) to dapagliflozin, allowing for use in a wider population depending on renal function, hepatic function and age.

For more detail on PBAC’s view, see section 7 “PBAC outcome”

7 PBAC Outcome

- 7.1 The PBAC recommended the PBS listing of empagliflozin in triple oral combination with metformin and a sulfonylurea on a cost minimisation basis with dapagliflozin. The equi-effective doses were empagliflozin 10mg or 25mg and dapagliflozin 10mg.
- 7.2 The PBAC recommended that the restriction permit a patient who had previously demonstrated that their diabetes was unable to be controlled with metformin or a sulfonylurea to access PBS subsidised empagliflozin without the need to requalify. The PBAC noted that this was consistent with the restriction for dapagliflozin.
- 7.3 The PBAC considered that there was no reason to exempt the empagliflozin from the Safety Net 20 Day Rule.
- 7.4 The PBAC advised that empagliflozin is suitable for prescribing by Nurse Practitioners for Continuing Therapy Only.
- 7.5 Under Section 101(3BA) of the *National Health Act 1953*, the PBAC advised that empagliflozin should be treated as interchangeable on an individual patient basis with dapagliflozin.

Outcome:

Recommended

8 Recommended listing

- 8.1 Amend existing/recommended listing as follows:

| Name, Restriction, Manner of administration and form | Max. Qty | No. of Rpts | Proprietary Name and Manufacturer | |
|--|----------|-------------|-----------------------------------|----------------------|
| EMPAGLIFLOZIN Film coated tablet, 10mg | 30 | 5 | Jardiance® | Boehringer Ingelheim |
| EMPAGLIFLOZIN Film coated tablet, 25mg | 30 | 5 | | |

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|------------------------------------|--|
| Category / Program | GENERAL – General Schedule (Code GE) |
| Prescriber type: | <input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives |
| Condition: | Diabetes mellitus type 2 |
| PBS Indication: | Diabetes mellitus type 2 |
| Restriction Level / Method: | <input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input checked="" type="checkbox"/> Streamlined |

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| <p>Clinical criteria:</p> | <p>The treatment must be in combination with metformin, AND</p> <p>The treatment must be in combination with a sulfonylurea, AND</p> <p>Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy;</p> <p>OR</p> <p>Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.</p> |
| <p>Prescriber Instructions</p> | <p>The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.</p> <p>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.</p> <p>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:</p> <p>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</p> <p>(b) Had red cell transfusion within the previous 3 months</p> <p>The result of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.</p> <p>A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.</p> |
| <p>Administrative Advice</p> | <p>Note: 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.</p> <p>Note: This drug is not PBS subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.</p> <p>PBS subsidised dual oral therapy does not include concomitant use of two of either: a gliptin, a glitazone or an SGLT2 inhibitor.</p> |

9 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final

PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

10 Sponsor's Comment

The sponsor had no comment.