

## 14.03 EXENATIDE

### Injection 2 mg per dose pre-filled pen, 4 Bydureon®, AstraZeneca Pty Ltd

#### 1 Purpose of Application

- 1.1 The submission requested that the July 2015 PBAC recommendation to list the single dose tray presentation of exenatide once weekly be applied to the dual chamber pen presentation.

#### 2 Requested Listing

- 2.1 The minor submission requested the same Section 85 Authority Required listings for dual and triple therapy (with metformin and/or a sulfonylurea) as recommended in the July 2015 Public Summary Document (PSD).

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

#### 3 Background

- 3.1 Exenatide 2 mg powder for injection once weekly (presented in a single dose tray) was TGA registered on 20 December 2012 for the treatment of Type 2 diabetes mellitus in combination with metformin, sulfonylureas or metformin and a sulfonylurea, in patients who have not achieved adequate glycaemic control. The dual chamber pen, which contains the same active ingredient as the single dose tray, was TGA registered from 25 June 2015.
- 3.2 At its November 2013 meeting, the PBAC recommended the listing of exenatide 2 mg once weekly as an Authority Required (Streamlined) benefit for dual combination therapy with metformin or a sulfonylurea and triple combination therapy with metformin and a sulfonylurea in patients with type 2 diabetes, on a cost-minimisation basis with exenatide 10 mcg twice daily.
- 3.3 At its July 2015 meeting, the PBAC re-endorsed its November 2013 recommendation (of cost-minimisation with a partial cost offset for reduced needle use) and recommended a further small price advantage for exenatide 2 mg once weekly on the basis of potential health benefits from likely improved adherence by a small number of high clinical need populations.
- 3.4 This was the fifth submission to the PBAC for exenatide 2 mg once weekly. Previous submissions were considered in July 2011, July 2013, November 2013 and July 2015.

#### 4 Pricing considerations

- 4.1 The price of exenatide once weekly is currently being negotiated between the Department and the sponsor in line with the July 2015 PBAC recommendation. The sponsor requested that this price apply to the dual chamber pen instead of the single dose tray presentation.

#### 5 PBAC Outcome

- 5.1 The PBAC recommended exenatide - Injection 2 mg per dose pre-filled pen as an Authority Required (Streamlined) benefit for the treatment of type 2 diabetes mellitus (T2DM), under the same circumstances and on the same basis as the recommendation for exenatide 2 mg single dose tray presentation.
- 5.2 At its July 2015 meeting, the PBAC re-endorsed its November 2013 recommendation (of cost-minimisation basis with a partial cost offset for reduce needle use) and had recommended exenatide 2 mg once weekly presentation on the basis of potential health benefits from likely improved adherence by a small number of high clinical need populations.
- 5.3 The PBAC noted that the requested restriction was in line with that recommended in November 2013 and in July 2015.
- 5.4 The PBAC advised that the Early Supply Rule should apply to exenatide once weekly.
- 5.5 The PBAC advised that exenatide once weekly was suitable for prescribing by nurse practitioners under collaborative arrangements.

#### Outcome:

Recommended

#### 6 Recommended listing

- 6.1 Recommended listing as follows:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
EXENATIDE exenatide 2 mg powder for injection, pre-filled pen, 4	1	5	Bydureon®	AstraZeneca

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Condition:</b>	Diabetes mellitus type 2
<b>PBS Indication:</b>	Diabetes mellitus type 2

Public Summary Document – March 2016 PBAC Meeting

<b>Restriction Level / Method:</b>	<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
<b>Clinical criteria:</b>	<p>The treatment must be in combination with metformin; OR            The treatment must be in combination with a sulfonylurea.</p> <p>AND</p> <p>Patient must have a contraindication to a combination of metformin and a sulfonylurea;            OR            Patient must not have tolerated a combination of metformin and a sulfonylurea.</p> <p>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 either metformin or a sulfonylurea; OR            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 either metformin or a sulfonylurea.</p>
<b>Prescriber Instructions:</b>	<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> <ol style="list-style-type: none"> <li>A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</li> <li>Had red cell transfusion within the previous 3 months</li> </ol> <p>The results 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>
<b>Administrative Advice:</b>	<p>Note:            This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), an insulin or an SGLT2 inhibitor.</p>

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Condition:</b>	Diabetes mellitus type 2
<b>PBS Indication:</b>	Diabetes mellitus type 2

Public Summary Document – March 2016 PBAC Meeting

<b>Restriction Level / Method:</b>	<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
<b>Clinical criteria:</b>	<p>The treatment must be in combination with metformin,</p> <p>AND</p> <p>The treatment must be in combination with a sulfonylurea,</p> <p>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; OR 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.</p>
<b>Prescriber Instructions:</b>	<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> <ul style="list-style-type: none"> <li>a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</li> <li>b) Had red cell transfusion within the previous 3 months</li> </ul> <p>The results 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>
<b>Administrative Advice:</b>	<p>Note:          This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), an insulin or an SGLT2 inhibitor.</p>

**7 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.

**8 Sponsor's Comment**

The sponsor had no comment.