

5.17 APOMORPHINE

Injection containing apomorphine hydrochloride

100 mg in 20 mL

Apomine[®],

Pfizer Australia Pty Ltd.

1 Purpose of Application

- 1.1 The minor submission requested a Section 100 Highly Specialised Drugs Program Authority Required listing of a new presentation of apomorphine (100 mg in 20 mL) for the treatment of Parkinson disease.

2 Requested listing

- 2.1 The submission requested the listing of the following new form, with the same restrictions as the existing listing:

- 2.2 Secretariat suggested changes are indicated in *italics* for additions and ~~strike through~~ for deletions.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
APOMORPHINE <i>Apomorphine hydrochloride hemihydrate</i> <i>5 mg/mL solution for infusion,</i> <i>100 mg/20 mL injection,</i> <i>5 x 20 mL vials</i>	18	5	\$ [REDACTED] (Public) \$ [REDACTED] (Private)	Apomine® Pfizer Australia Pty Ltd

Category / Program	Section 100 – Highly Specialised Drugs Program
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
PBS Indication:	Parkinson Disease
Restriction Level / Method:	<input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required - Electronic <input checked="" type="checkbox"/> Streamlined
Clinical criteria:	Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.

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

3 Background

- 3.1 Apomorphine 100 mg in 20 mL vial was approved by the TGA on 20 July 2016 and registered on the ARTG on the 16 August 2016.
- 3.2 Apomorphine is currently available on the PBS as 10 mg in 1 mL ampoule, 20 mg in 2 mL ampoule and 50 mg in 5 mL ampoule as a section 100 HSD listing for the treatment of patients with Parkinson disease with severely disabling motor fluctuations which have not responded to other therapy.
- 3.3 The minor submission stated that the daily dose of apomorphine for patients treated with continuous infusion ranges from 4 mg to 7 mg per hour for 12 to 24 hours, which equates to a daily dose of 64 mg to 168 mg. Therefore, in order to use the currently PBS listed presentations of apomorphine, multiple ampoules are required to obtain the required dose, along with dilution with sodium chloride. The listing of the 100 mg in 20 mL presentation of apomorphine would eliminate these requirements.

4 Consideration of the evidence

Sponsor hearing

- 4.1 There was no hearing for this item as it was a minor submission.

Consumer comments

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

Estimated PBS usage & financial implications

- 4.3 The sponsor proposed equivalent price per mg as the 10 mg in 1 mL ampoule presentation currently listed on the PBS and proposed an AEMP for apomorphine 5 mg/mL, 5 x 20 mL vials of \$420.16. The PBAC agreed with the proposed equivalent price per mg, but noted that this would result in an AEMP of \$419.60 for apomorphine 5 mg/mL, 5 x 20 mL vials.
- 4.4 The PBAC considered that the listing of the 100 mg in 20 mL presentation of apomorphine would not have any financial implications to the PBS, as it will substitute for currently available PBS therapies at the same price. However, the PBAC noted that as the submission did not provide any patient and dosing data, and considered that the Department should negotiate with the sponsor to ensure that there was nil financial impact as a result of this listing.

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

5 PBAC Outcome

- 5.1 The PBAC recommended the listing of apomorphine 100 mg in 20 mL at an equivalent price per mg to the current 10 mg in 1 mL ampoule presentation listed on the PBS.
- 5.2 The PBAC acknowledged that this new presentation offered some benefits to patients using a continuous infusion pump as it means that multiple ampoules will not be needed to obtain the required dose.
- 5.3 The PBAC noted that this form was at a different concentration to the currently listed forms of apomorphine, which presented a quality use of medicines issue due to the potential for confusion, and considered that the sponsor should ensure clear communications regarding this difference.
- 5.4 Consistent with the existing arrangements for the current strengths, the PBAC advised that apomorphine is not suitable for prescribing by nurse practitioners.
- 5.5 The PBAC advised that the Early Supply Rule should not apply as it does not apply to Section 100 items or for the other forms of apomorphine.
- 5.6 The PBAC noted that this submission is not eligible for independent review as it received a positive recommendation.

Outcome:

Recommended

6 Recommended listing

Add new item:

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Category / Program	Section 100 – Highly Specialised Drugs Program
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PBS Indication:	Parkinson Disease

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Clinical criteria:	Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.

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.