

## 5.15 APOMORPHINE

### Injection containing apomorphine hydrochloride

### 30 mg in 3 mL cartridge

### Apomine<sup>®</sup> Intermittent, 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 form of apomorphine, Apomine<sup>®</sup> Intermittent (30 mg in 3 mL cartridge) for the treatment of Parkinson's disease (PD).

## 2 Requested listing

- 2.1 Secretariat suggested changes are indicated in italics for additions and strikethrough for deletions.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
A POMORPHINE apomorphine hydrochloride <del>hemihydrate</del> Injection cartridge 30 mg/3 mL <i>injection, 5 × 3 mL cartridges</i>	<del>4220</del>	5	\$ [REDACTED] (Public hospital) \$ [REDACTED] (Private hospital)	Apomine <sup>®</sup> Intermittent Pfizer Australia Pty Ltd

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

## 3 Background

- 3.1 Apomorphine injectable formulations have been registered with the TGA since they were grandfathered onto the Australian Register of Therapeutic Goods on 8 October 1991 for the treatment of patients with PD with severely disabling motor fluctuations that have not responded to other therapy. This product, Apomine<sup>®</sup> Intermittent (apomorphine hydrochloride hemihydrate) 30 mg in 3 mL injection cartridge, was added to the Australian Register of Therapeutic Goods (ARTG) on 7 June 2018.

- 3.2 Apomorphine is currently available on the PBS in ampoule forms (20 mg/2 mL, 50 mg/5 mL and 100 mg/20 mL) for continuous and intermittent subcutaneous injection, and in a pre-filled syringe form (50 mg/10 mL) for continuous subcutaneous infusion.
- 3.3 The maximum quantity in the sponsor's requested listing, 12 packs, is sufficient for 36 days' supply at the maximum daily dose of 50 mg for intermittent use. The pre-PBAC response suggested the maximum quantity of apomorphine 30 mg in 3 mL should be increased to 60 packs, to align with the other PBS-listed forms of apomorphine. However, this form of apomorphine is specifically designed for intermittent use only, and this would result in 180 days' supply at the maximum daily dose for intermittent use. Conversely, the existing forms of 10 mg/mL apomorphine listed on the PBS can be used both intermittently and continuously, and supply 45 days at the maximum daily dose of 200 mg per day for continuous use. The PBAC therefore advised that the maximum quantity for this presentation of apomorphine should be 20 packs, sufficient for two months' supply at the maximum daily dose for intermittent use, as is standard for drugs on the Highly Specialised Drugs Program.
- 3.4 At its March 2018 meeting, the PBAC recommended the listing of a new form of apomorphine, an injection cartridge delivered in a disposable multiple dose pen injector system (30 mg in 3 mL) for intermittent bolus subcutaneous injection. This was the first form of apomorphine with a self/carer-injection delivery method to be recommended for listing on the PBS. If apomorphine 30 mg in 3 mL is recommended for listing, it will be the second form of apomorphine with this delivery method to be included on the PBS. This new form delivers apomorphine using a reusable injection device, rather than a disposable device.

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

## **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.

### ***Clinical trials***

- 4.3 As a minor submission, no clinical trials were presented in the submission.

### ***Clinical claim***

- 4.4 As an additional presentation, the submission assumed that the new form was non-inferior to the currently listed forms. The submission claimed that the reusable

multi-dose pen injector provides benefits as it allows 0.5 mg increments in dosage, unlike other forms, and includes a safety feature that facilitates administration for patients with motor impairment. The Secretariat noted that, while the submission claimed this pen is a more efficient, less wasteful, and safer form of administration than those currently available on the PBS, it did not provide any evidence to support these claims.

### ***Estimated PBS usage & financial implications***

- 4.5 The submission did not include a financial estimates model.
- 4.6 The minor submission estimated that there would be no changes in PBS usage if this form of apomorphine were to be listed, as it is expected to be a substitute for already listed forms. The proposed price per mg is equivalent to the lowest price 10 mg in 1 mL presentation of apomorphine currently listed on the PBS.
- 4.7 The sponsor was requested to provide information on the expected financial impact in its pre-PBAC response. The sponsor suggested that the financial impact was expected to be nil.

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

## **5 PBAC Outcome**

- 5.1 The PBAC recommended the Authority Required listing of a new form of apomorphine (30 mg in 3 mL) delivered in a disposable multiple dose pen injector system for the treatment of Parkinson's disease (PD), on the basis that it should be available under Section 100, Highly Specialised Drugs (HSD) Program.
- 5.2 The PBAC accepted the sponsor's claim that this form of apomorphine would substitute existing use of the currently PBS-listed forms of apomorphine, without increasing the overall utilisation. As such, and given that the sponsor requested a price equivalent to the lowest price currently listed for apomorphine, the PBAC agreed that this listing was likely to have negligible net financial implications for the PBS.
- 5.3 The PBAC advised that the maximum quantity for this listing should provide for two months' supply, as is standard for the S100 HSD Program. A maximum quantity of 20 packs would provide for 2 months' treatment at the maximum daily dose of 50 mg for intermittent use. The PBAC acknowledged that other intermittent forms of apomorphine have maximum quantities sufficient for up to 180 days' supply at the maximum daily dose of 50 mg. The PBAC noted that this is because they are suitable for use in both intermittent and continuous treatment, and the maximum daily dose for continuous use is 200 mg, which would result in 45 days' treatment at the maximum quantity.
- 5.4 The PBAC advised that, under Section 101 (4AACD) of the *National Health Act 1953*, Apomine Intermittent 30 mg in 3 mL injection could be treated as equivalent to

Movapo 30 mg in 3 mL injection for the purposes of substitution at the pharmacy level. The Committee noted that Movapo is administered via a disposable injector pen, while this form (Apomine Intermittent) uses a reusable injector pen, and considered this difference could be managed through the regular patient education and counselling that is provided to patients by prescribers and pharmacists.

- 5.5 The PBAC advised that apomorphine is not suitable for prescribing by nurse practitioners.
- 5.6 The PBAC advised that the Early Supply Rule should not apply as it currently does not apply to Section 100 items or for the other forms of apomorphine.
- 5.7 The PBAC noted that this submission is not eligible for an Independent Review because it received a positive recommendation.

**Outcome:**

Recommended

## 6 Recommended Listing

- 6.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	Nº.of Rpts	Proprietary Name and Manufacturer	
APOMORPHINE apomorphine hydrochloride 30 mg/3 mL injection, 5 × 3 mL cartridge	20	5	Apomine® Intermittent	Pfizer Australia Pty Ltd
<b>Category / Program</b>	Section 100 – Highly Specialised Drugs Program			
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives			
<b>PBS Indication:</b>	Parkinson Disease			
<b>Restriction Level / Method:</b>	<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 (Public only)			
<b>Clinical criteria:</b>	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.