

14.3 MINOR LISTINGS AND CHANGES TO LISTINGS PROCESSED BY THE SECRETARIAT

APOMORPHINE HYDROCHLORIDE

**Injection, 10 mg in 1 mL,
Apomine[®], Hospira Pty Ltd**

1 Purpose of application

- 1.1 The submission requested a Section 100 (Highly Specialised Drugs Program) Authority Required listing of a lower strength presentation (10 mg in 1 mL) for the management of advanced Parkinson disease.

2 PBAC Outcome

- 2.1 The PBAC recommended listing of the 10 mg in 1 mL presentation of apomorphine at the same price per mg as the 20 mg in 2 mL presentation currently listed on the PBS.
- 2.2 The PBAC recommended listing under the same conditions as the existing listing for the 20 mg in 2 mL presentation.
- 2.3 Consistent with the existing arrangements for the current strengths, the PBAC advised that the new apomorphine strength is not suitable for prescribing by nurse practitioners.
- 2.4 As a Section 100 item, the PBAC noted that the Safety Net 20 Day Rule should not apply.

Outcome:

Recommended

3 Recommended listing

Add new item:

Public Summary Document – November 2014 PBAC Meeting

Name, Restriction, Manner of administration and form	Max. Qty (Packs)	Max. Qty (Units)	No. of Rpts	Proprietary Name and Manufacturer
APOMORPHINE apomorphine hydrochloride 10 mg/1 mL injection, 5 x 1 mL ampoules	72	360	5	Apomine HH

Category / Program	Section 100 – Highly Specialised Drugs Program – Public Hospitals
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
Episodicity:	-
Severity:	-
Condition:	Parkinson disease
PBS Indication:	Parkinson disease
Treatment phase:	-
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
Clinical criteria:	Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy

Category / Program	Section 100 – Highly Specialised Drugs Program – Private Hospitals
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
Episodicity:	-
Severity:	-
Condition:	Parkinson disease
PBS Indication:	Parkinson disease
Treatment phase:	-
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <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 type="checkbox"/> Streamlined
Clinical criteria:	Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy

4 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.

5 Sponsor's Comment

The sponsor had no comment.