

5.18 APOMORPHINE

50 mg / 10 mL, injection, pre-filled syringe

MOVAPO[®] PFS, STADA Pharmaceuticals Australia Pty Ltd

1 Purpose of Application

- 1.1 The minor submission requested the re-listing of apomorphine pre-filled syringe 50 mg / 10 mL under a new brand name (MOVAPO[®] PFS) as an Authority Required pharmaceutical benefit on the *Section 100 Highly Specialised Drugs Program (Private and Public Hospitals) Schedule* for the treatment of Parkinson's disease.

2 Requested listing

- 2.1 The submission requested the following new listing.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Manufacturer	Name and
APOMORPHINE Apomorphine hydrochloride 50 mg/10 mL injection: subcutaneous infusion, 5 x 10 mL syringes	36	5	MOVAPO [®] PFS	STADA Pharmaceuticals 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
Condition:	Parkinson disease
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.

- 2.2 No changes to the requested restriction of apomorphine were proposed.

For more detail of the PBAC's view, see section 5 'PBAC outcome'.

3 Background

- 3.1 Apomorphine injectables have been registered with the TGA since they were grandfathered onto the Australian Register of Therapeutic Goods on 8 October 1991.

- 3.2 Apomorphine pre-filled syringe (PFS) was TGA registered on 29 July 2008 under its original trade name (APOMINE[®] PFS) and is indicated to reduce the number and severity of ‘off’ phases in patients with Parkinson’s disease severely disabled by motor fluctuations refractory to conventional therapy.
- 3.3 APOMINE[®] PFS was delisted from the PBS on 1 August 2015. The availability of a pre-filled syringe option provides benefits to patients in terms of its ease of use and lower risk of needle stick injury compared to other injectable forms of apomorphine that also are administered via continuous subcutaneous infusion. In their pre-PBAC response, the sponsor indicated that the pre-filled syringe also addresses the risk of injury caused by opening the ampoule, and contains less of the preservative sodium metabisulphite (0.05% compared to 0.1%).
- 3.4 The PBAC has previously considered submissions requesting the listing of other forms and strengths of apomorphine (10 mg / 1 mL in November 2014 and 50 mg / 5 mL in March 2009) and has recommended the listing under the same conditions and at the same price per mg as the 20 mg in 2 mL presentation.

4 Consideration of the evidence

Estimated PBS usage & financial implications

- 4.1 The minor submission used a market share approach to estimate utilisation. The submission estimated there to be no financial implications to the PBS as the submission expects MOVAPO PFS 50 mg / 10 mL to directly substitute for MOVAPO[®] injection 50 mg / 5 mL and both drugs have the same price.

For more detail of the PBAC’s view, see section 5 ‘PBAC outcome’.

5 PBAC Outcome

- 5.1 The PBAC recommended the listing of apomorphine 50 mg / 10 mL, injection, pre-filled syringe (MOVAPO[®] PFS) on the basis that it should be available only under special arrangements under Section 100 (Highly Specialised Drugs Program), with the special requirements consistent with the PBS listing of MOVAPO[®] injection 50 mg / 5 mL.
- 5.2 The PBAC recommended that apomorphine 50 mg / 10 mL, injection, pre-filled syringe be PBS-listed on the same price per mg basis as the MOVAPO[®] injection 50 mg / 5 mL.
- 5.3 The PBAC advised that apomorphine 50 mg / 10 mL, injection, pre-filled syringe is not suitable for prescribing by nurse practitioners.
- 5.4 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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APOMORPHINE Apomorphine hydrochloride 50 mg/10 mL injection: subcutaneous infusion, 5 x 10 mL syringes	36	5	MOVAPO® PFS	STADA Pharmaceuticals 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
Condition:	Parkinson disease
Restriction Level / Method:	<input checked="" type="checkbox"/> Streamlined
Clinical criteria:	Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Manufacturer	Name and
APOMORPHINE Apomorphine hydrochloride 50 mg/10 mL injection: subcutaneous infusion, 5 x 10 mL syringes	36	5	MOVAPO® PFS	STADA Pharmaceuticals Australia Pty Ltd

Category / Program	Section 100 – Highly Specialised Drugs Program Private Hospital
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
Condition:	Parkinson disease
Restriction Level / Method:	<input checked="" type="checkbox"/> Authority Required - Emergency <input checked="" type="checkbox"/> Authority Required Written <input checked="" type="checkbox"/> Authority Required Telephone <input checked="" type="checkbox"/> Authority Required Electronic
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.