

6.08 APOMORPHINE

Injection containing apomorphine hydrochloride hemihydrate 100 mg in 20 mL, Apomine® Solution for Infusion,

Solution for subcutaneous injection containing apomorphine hydrochloride 30 mg in 3 mL pre-filled pen, Apomine® Intermittent, Pfizer Australia Pty Ltd.

1 Purpose of Application

- 1.1 The minor submission sought to extend the current listing of apomorphine 100 mg in 20 mL injection and apomorphine 30 mg in 3 mL injection for the treatment of Parkinson's disease to include General Schedule Authority Required (STREAMLINED) listings for continuing treatment following initiation in a hospital setting under the current Section 100 Highly Specialised Drugs (HSD) Program listing.

2 Background

- 2.1 In November 2016, the PBAC recommended the Section 100 HSD Authority Required listing of apomorphine 100 mg in 20 mL (Apomine solution for infusion) for the treatment of Parkinson's disease (PD) at an equivalent price per mg to the 10 mg in 1 mL ampoule presentation (Movapo®).
- 2.2 In July 2018, the PBAC recommended the Section 100 HSD Authority Required listing of apomorphine 30 mg in 3 mL (Apomine Intermittent) for the treatment of PD. The PBAC advised that Apomine Intermittent should be treated as equivalent for the purpose of substitution at the pharmacy level (i.e. 'a'-flagged) with Movapo Pen.
- 2.3 Levodopa with carbidopa intestinal gel (Duodopa®) for the management of advanced Parkinson disease in a patient with severe disabling motor fluctuations not adequately controlled by oral therapy was recommended by the PBAC in November 2010 as a dual listing under Section 100 (HSD) and the General Schedule.

3 Requested listing

- 3.1 The submission requested the following change to existing Section 100 listings (proposed additions in italics):

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Name, Restriction, Manner of administration and form	PBS item code	Max. Qty packs	Max. Qty units	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer	
APOMORPHINE 100 mg/20 mL injection, 5 x 20 mL vials	11083H ^a 11093W ^b	18	90	5	\$7600.15 (public) \$7552.80 (Private)	Apomine® Solution for Infusion	Pfizer Australia Pty Ltd

Category / Program: Section 100 (Highly Specialised Drugs) - Public Hospital (Code HB) Section 100 (Highly Specialised Drugs) - Private Hospital (Code HS)
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
Restriction Level / Method: <input type="checkbox"/> Unrestricted benefit <input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – In Writing <input type="checkbox"/> Authority Required – Telephone/Electronic/Emergency <input checked="" type="checkbox"/> Authority Required - Streamlined
Indication: Parkinson disease
Clinical criteria: Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy
AND
Clinical criteria: <i>The treatment must be commenced in a hospital-based movement disorder clinic</i>

Name, Restriction, Manner of administration and form	PBS item code	Max. Qty packs	Max. Qty units	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer	
APOMORPHINE 30 mg/3 mL injection, 5 x 3 mL cartridges	11672H ^a 11688E ^b	20	100	5	\$2720.40 (Public) \$2767.79 (Private)	Apomine® Intermittent	Pfizer Australia Pty Ltd

Category / Program: Section 100 (Highly Specialised Drugs) - Public Hospital (Code HB) Section 100 (Highly Specialised Drugs) - Private Hospital (Code HS)
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
Restriction Level / Method: <input type="checkbox"/> Unrestricted benefit <input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – In Writing <input type="checkbox"/> Authority Required – Telephone/Electronic/Emergency <input checked="" type="checkbox"/> Authority Required - Streamlined
Indication: Parkinson disease
Clinical criteria: Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy
AND
Clinical criteria: <i>The treatment must be commenced in a hospital-based movement disorder clinic</i>
Administrative Advice: Pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL pen device and pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL cartridge are equivalent for the purposes of substitution.
Administrative Advice: No increase in the maximum quantity or number of units may be authorised.

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3.2 The submission requested the following new listings:

Name, Restriction, Manner of administration and form	PBS item code	Max. Qty packs	Max. Qty units	№.of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer	
APOMORPHINE 100 mg/20 mL injection, 5 x 20 mL vials	NEW	18	90	5	\$7704.92	Apomine® Solution for Infusion	Pfizer Australia Pty Ltd

Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Restriction Level / Method: <input type="checkbox"/> Unrestricted benefit <input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – In Writing <input type="checkbox"/> Authority Required – Telephone/Electronic/Emergency <input checked="" type="checkbox"/> Authority Required - Streamlined
Indication: Parkinson disease
Treatment Phase: Maintenance therapy
Clinical criteria: Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy
AND
Clinical criteria: The treatment must be commenced in a hospital-based movement disorder clinic

Name, Restriction, Manner of administration and form	PBS item code	Max. Qty packs	Max. Qty units	№.of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer	
APOMORPHINE 30 mg/3 mL injection, 5 x 3 mL cartridges	NEW	20	100	5	\$2872.52	Apomine® Intermittent	Pfizer Australia Pty Ltd

Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Restriction Level / Method: <input type="checkbox"/> Unrestricted benefit <input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – In Writing <input type="checkbox"/> Authority Required – Telephone/Electronic/Emergency <input checked="" type="checkbox"/> Authority Required - Streamlined
Indication: Parkinson disease
Treatment Phase: Maintenance therapy
Clinical criteria: Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy
AND
Clinical criteria: The treatment must have been commenced in a hospital-based movement disorder clinic

Administrative Advice: Pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL pen device and pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL cartridge are equivalent for the purposes of substitution.
Administrative Advice: No increase in the maximum quantity or number of units may be authorised.

- 3.3 The requested General Schedule listing for maintenance therapy would allow PD patients access to apomorphine through a community pharmacy. This was consistent with the dual Section 100 and General Schedule listings for Duodopa for advanced PD.

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.

Estimated PBS usage & financial implications

- 4.3 The submission provided two estimates of the proportion of prescriptions that would transition from being dispensed under the existing Section 100 HSD listing to a new General Schedule listing. One estimate was based on the proportion of prescriptions for sirolimus that transitioned to being dispensed under the general schedule listing (75.53%) after originally being listed solely under Section 100. The second estimate was based on the distribution of prescriptions of levodopa with carbidopa intestinal gel dispensed under the general schedule (95.79%), noting that the product has always had a dual listing on both Section 100 and the General Schedule.
- 4.4 The minor submission estimated a net cost of less than \$10 million or less than \$10 million per year of listing, based on 95.79% or 75.53% scripts being prescribed under the General Schedule, respectively (see Table 1). These costs were due to the additional mark-ups applied to General Schedule listings, compared with Section 100 HSD Public and Private Hospital listings.

Table 1: Estimated use and financial implications for apomorphine extended into General Schedule

	Estimated portion of scripts to transition to General Schedule	
	95.79% (based on levodopa + carbidopa)	75.53% (based on sirolimus)
Estimated extent of use on the General Schedule^a		
Apomine solution for infusion		
Apomine intermittent ^b		
Estimated financial implications of General Schedule listings of Apomine solution for infusion, Apomine intermittent.		
Cost to PBS/RPBS less copayments ^c	\$	\$
Estimated financial implications for HSD (public and private hospital) listing of Apomine solution for infusion, Apomine solution for infusion, and Apomine intermittent.(Item codes 11093W, 11083H, 11672H, and 11688E)		
Cost to PBS/RPBS less copayments	\$	\$
Net financial implications		
Net cost to PBS/RPBS	\$	\$

^a Based on current utilisation October 2018 to September 2019.

^b PBS listed in May 2019

^c Based on current average co-payments estimated to be \$11.14 for Apomine Solution of Infusion and \$18.75 for Apomine Intermittent

Source: Submission financial calculations spreadsheet.

- 4.5 The submission claimed its utilisation estimates were based on 12 months of data (October 2018 to September 2019), however as Apomine Intermittent was only PBS listed on 1 May 2019, the estimated extent of use was based on only 5 months of data. Accordingly, the financial estimates presented in the submission were underestimated.
- 4.6 Further, the estimates did not account for Movapo Pen 30 mg in 3 mL, which is ‘a’ flagged to Apomine Intermittent, also having a dual listing on the General Schedule. It was estimated, based on utilisation data from May 2019 to September 2019 that 89% of apomorphine 30 mg/3 mL injection scripts were for Movapo Pen.
- 4.7 The minor submission assumed that there would be no net increase in utilisation of apomorphine as a result of the additional General Schedule listing for maintenance treatment.

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

5 PBAC Outcome

- 5.1 The PBAC recommended extending the current listing of apomorphine 100 mg in 20 mL injection and 30 mg in 3 mL injection to include a listing under the General Schedule as an Authority Required (STREAMLINED) listing for patients requiring maintenance treatment of Parkinson Disease (PD), at a price which would be cost-neutral to Section 100 HSD listings.
- 5.2 The PBAC considered it was clinically appropriate for maintenance treatment with apomorphine to be prescribed outside of a hospital setting, provided treatment commences in hospital.

- 5.3 The PBAC recalled its July 2018 advice that Movapo Pen 30 mg in 3 mL injection is equivalent to Apomine Intermittent 30 mg in 3 mL injection for the purpose of substitution at the pharmacy level (paragraph 5.4 Apomorphine Public Summary Document, July 2018 PBAC meeting). The PBAC therefore advised that it is reasonable for the changes to apply to both Apomine Intermittent and to Movapo Pen.
- 5.4 The PBAC considered it appropriate to include the restriction criterion ‘the treatment must be commenced in a hospital-based movement disorder clinic’ to both General Schedule and Section 100 HSD listings.
- 5.5 The PBAC noted the financial estimates provided by the submission were underestimated and should be adjusted to account for 12 months of data for Apomine intermittent and the flow on change to Movapo Pen.
- 5.6 The PBAC recalled that it previously advised that, where a recommendation is made to move a drug from Section 100 to General Schedule, the cost of the increased pharmacy remuneration should be borne by the manufacturer. The PBAC therefore considered that the sponsor should reduce the ex-manufacturer price of apomorphine 100 mg in 20 mL injection and 30 mg in 3 mL injection to ensure that the impact to government would remain cost neutral for a dual Section 100 and General Schedule listing of apomorphine.
- 5.7 The PBAC advised that the new apomorphine listings on the General Schedule are suitable for prescribing by nurse practitioners under a Shared Care model. This is consistent with the General Schedule listing of Duodopa.
- 5.8 The PBAC recommended that the Early Supply Rule should not apply as it currently does not apply for the other forms of apomorphine.
- 5.9 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

6 Recommended listing

6.1 Changes to the existing listing:

Name, Restriction, Manner of administration and form	PBS item code	Max. Qty packs	Max. Qty units	№.of Rpts	Proprietary Name and Manufacturer	
APOMORPHINE 100 mg/20 mL injection, 5 x 20 mL vials	11083H 11093W	18	90	5	Apomine® Solution for Infusion	Pfizer Australia Pty Ltd

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Restriction Summary [4833] / Treatment of Concept: [4833]

Category / Program: Section 100 (Highly Specialised Drugs) - Public Hospital (Code HB) Section 100 (Highly Specialised Drugs) - Private Hospital (Code HS)
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
Restriction Level / Method: <input type="checkbox"/> Unrestricted benefit <input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – In Writing <input type="checkbox"/> Authority Required – Telephone/Electronic/Emergency <input checked="" type="checkbox"/> Authority Required - Streamlined
Indication: Parkinson disease
Clinical criteria: Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy
AND The treatment must be commenced in a specialist unit in a hospital setting

Name, Restriction, Manner of administration and form	PBS item code	Max. Qty packs	Max. Qty units	No. of Rpts	Proprietary Manufacturer	Name and
APOMORPHINE 30 mg/3 mL injection, 5 x 3 mL cartridges	11672H 11688E	20	100	5	Apomine® Intermittent	Pfizer Australia Pty Ltd
APOMORPHINE 30 mg/3 mL injection, 5 x 3 mL pen devices	11475Y 11477C	20	100	5	Movapo®	STADA Pharmaceuticals Australia Pty Ltd

Restriction Summary [4833] / Treatment of Concept: [4833]

Category / Program: Section 100 (Highly Specialised Drugs) - Public Hospital (Code HB) Section 100 (Highly Specialised Drugs) - Private Hospital (Code HS)
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
Restriction Level / Method: <input type="checkbox"/> Unrestricted benefit <input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – In Writing <input type="checkbox"/> Authority Required – Telephone/Electronic/Emergency <input checked="" type="checkbox"/> Authority Required - Streamlined
Indication: Parkinson disease
Clinical criteria: Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy
AND The treatment must be commenced in a specialist unit in a hospital setting
Administrative Advice: Pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL pen device and pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL cartridge are equivalent for the purposes of substitution.
Administrative Advice: No increase in the maximum quantity or number of units may be authorised.

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6.2 Add new item:

Name, Restriction, Manner of administration and form	PBS item code	Max. Qty packs	Max. Qty units	No. of Rpts	Proprietary Manufacturer	Name and
APOMORHPINE 100 mg/20 mL injection, 5 x 20 mL vials	NEW	18	90	5	Apomine® Solution for Infusion	Pfizer Australia Pty Ltd

Restriction Summary [new] / Treatment of Concept: [new]

Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Restriction Level / Method: <input type="checkbox"/> Unrestricted benefit <input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – In Writing <input type="checkbox"/> Authority Required – Telephone/Electronic/Emergency <input checked="" type="checkbox"/> Authority Required - Streamlined
Indication: Parkinson Disease
Treatment Phase: Maintenance therapy
Clinical criteria: Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy
AND
Clinical criteria: Patient must be have been commenced on treatment in a specialist unit in a hospital setting
Administrative Advice: Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Name, Restriction, Manner of administration and form	PBS item code	Max. Qty packs	Max. Qty units	No. of Rpts	Proprietary Name and Manufacturer	
APOMORPHINE 30 mg/3 mL injection, 5 x 3 mL cartridges	NEW	20	100	5	Apomine® Intermittent	Pfizer Australia Pty Ltd
APOMORPHINE 30 mg/3 mL injection, 5 x 3 mL pen devices	NEW	20	100	5	Movapo®	STADA Pharmaceuticals Australia Pty Ltd

Restriction Summary [new] / Treatment of Concept: [new]

Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Restriction Level / Method: <input type="checkbox"/> Unrestricted benefit <input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – In Writing <input type="checkbox"/> Authority Required – Telephone/Electronic/Emergency <input checked="" type="checkbox"/> Authority Required - Streamlined
Indication: Parkinson Disease
Treatment Phase: Maintenance therapy
Clinical criteria: Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy
AND

Clinical criteria: Patient must be have been commenced on treatment in a specialist unit in a hospital setting
Administrative Advice: Pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL pen device and pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL cartridge are equivalent for the purposes of substitution.
Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
Administrative Advice: Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

These restrictions may be subject to further review. Should there be any changes made to the restriction the Sponsor will be informed.

7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

8 Sponsor's Comment

The sponsor had no comment.