

**5.18 APOMORPHINE,
Injection containing apomorphine hydrochloride
hemihydrate 100 mg in 20 mL,
Movapo® POD,
STADA Pharmaceuticals Australia Pty Limited**

1 Purpose of Submission

- 1.1 The Committee Secretariat submission requested General Schedule Authority Required (STREAMLINED) and Section 100 (Highly Specialised Drugs Program) (S100 HSD) Authority Required (STREAMLINED) listings of a new form of apomorphine (injection containing apomorphine hydrochloride hemihydrate 100 mg in 20 mL; herein referred to as Movapo® POD) under the same circumstances as apomorphine hydrochloride hemihydrate 100 mg/20 mL injection, 5 x 20 mL vials (herein referred to as Apomine® Solution for Infusion) currently listed on the Pharmaceutical Benefits Scheme (PBS), for the treatment of Parkinson disease.
- 1.2 Listing was requested on a cost-minimisation basis versus Apomine® Solution for Infusion currently listed on the PBS.

2 Background

- 2.1 Apomorphine hydrochloride hemihydrate is currently listed on the PBS for Parkinson disease as Authority Required (STREAMLINED) listings on the General Schedule and S100 HSD (Public and Private) in the following forms:
 - 30 mg/3 mL injection, 3 mL cartridges (Apomine Intermittent)
 - 30 mg/3 mL injection, 3 mL pen devices (Movapo Pen)
 - 50 mg/5 mL injection, 5 mL ampoules (Movapo)
 - 50 mg/10 mL injection, 10 mL syringes (Movapo PFS)
 - 100 mg/20 mL injection, 20 mL vials (Apomine Solution for Infusion).
- 2.2 The submission stated that the sponsor intends to discontinue Movapo 50 mg/10 mL (Movapo PFS) due to a change in manufacturing, and it anticipates patients currently using Movapo PFS will switch to using Movapo POD, if listed on the PBS.
- 2.3 Movapo POD is bioequivalent to Apomine Solution for Infusion (see paragraph 2.5), however has a different pump attachment mechanism. The submission stated the sponsor previously sought to list Movapo POD via the generic listing PBS pathway (new brand submission), however were advised it required consideration by the Pharmaceutical Benefits Advisory Committee (PBAC) due to the different pump attachment mechanism.

Registration status

- 2.4 Movapo POD was Therapeutic Goods Administration (TGA) registered on 29 August 2024 for the following indication: ‘to reduce the number and severity of ‘off’ phases in patients with Parkinson’s disease severely disabled by motor fluctuations refractory to conventional therapy. Initiation of therapy with apomorphine should be undertaken in a specialist unit in a hospital setting. Conventional therapy should be continued during ‘on’ phases’ (p1, Movapo POD Product Information). This indication aligns with the TGA-registered indication for other apomorphine products listed on the PBS.
- 2.5 The TGA Approval Letter for Movapo POD stated that the application for registration included data that established to the TGA’s satisfaction that it can be considered bioequivalent to Apomine 100 mg/20 mL. The sponsor noted that Movapo POD and Apomine Solution for Infusion are not interchangeable as both products have different presentations (see paragraph 2.3).

Previous PBAC consideration

- 2.6 Movapo POD has not been considered by the PBAC previously.
- 2.7 At its July 2016 meeting, the PBAC recommended listing Movapo PFS (50 mg/10 mL injection) on the PBS under the S100 HSD for Parkinson Disease (paragraph 5.1, apomorphine, Public Summary Document (PSD), July 2016 PBAC meeting).
- 2.8 At its November 2016 meeting, the PBAC recommended listing Apomine (100 mg/20 mL) on the PBS. The PBAC acknowledged that this 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 (paragraphs 5.1 and 5.2, apomorphine, PSD, November 2016 PBAC meeting).
- 2.9 Movapo Pen (30 mg/3 mL) was recommended for listing by the PBAC at its March 2018 meeting, and Apomine Intermittent (30 mg/3 mL) was recommended at the July 2018 PBAC meeting.
- 2.10 At its March 2020 meeting, the PBAC recommended extending the listing of Apomine Solution for Infusion (100 mg/20 mL) and Apomine Intermittent (30 mg/3 mL) to include a General Schedule, Authority Required (STREAMLINED) listing for patients requiring maintenance treatment of Parkinson Disease at a price which would be cost-neutral to the S100 HSD listings (paragraph 5.1, apomorphine, PSD, March 2020 PBAC meeting). The PBAC advised it was reasonable for the changes to also apply to Movapo Pen (paragraph 5.3, apomorphine, PSD, March 2020 PBAC Meeting).
- 2.11 At its November 2020 meeting, the PBAC recommended extending the listing of Movapo PFS (50 mg/10 mL) for the treatment of Parkinson disease to include General Schedule Authority Required (STREAMLINED) listings for maintenance therapy (paragraph 5.1, apomorphine, PSD, November 2020 PBAC meeting). The PBAC recommended that, to ensure consistency, it would be reasonable for the current

listings of Movapo (50 mg/5 mL) to also be extended to include General Schedule, Authority Required (STREAMLINED) listings for maintenance therapy (paragraph 5.5, apomorphine, PSD, November 2020 PBAC meeting).

3 Requested listing

3.1 The submission requested the following new listings:

Add new medicinal product pack as follows:

3.2 Suggestions and additions proposed by the Secretariat are added in italics.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
APOMORPHINE					
apomorphine hydrochloride hemihydrate 100 mg/20 mL injection, 5 x 20 mL cartridges	NEW	18	90	5	Movapo POD
Restriction Summary 10720/ Treatment of Concept: 10844					
Concept ID (for internal Dept. use)	Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined) [10844]				
	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 have been commenced on treatment in a specialist unit in a hospital setting.				

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60 days listing:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
APOMORPHINE					
apomorphine hydrochloride hemihydrate 100 mg/20 mL injection, 5 x 20 mL cartridges	NEW	36	180	5	Movapo POD
Restriction Summary 15541 / Treatment of Concept: 15542					
Concept ID (for internal Dept. use)	Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined) [15542]				
	Indication: Parkinson Disease				
	Treatment Phase: Maintenance therapy				
	Clinical criteria:				
	<i>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient,</i>				
	AND				
	Clinical criteria:				
	Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy,				
	AND				
	Clinical criteria:				
	Patient must have been commenced on treatment in a specialist unit in a hospital setting.				

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
APOMORPHINE					
apomorphine hydrochloride hemihydrate 100 mg/20 mL injection, 5 x 20 mL cartridges	NEW (HSD Public) NEW (HSD Private)	18	90	5	Movapo POD
Restriction Summary 10793/10864 / Treatment of Concept: 10830/10863					
Concept ID (for internal Dept. use)	Category / Program: <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Private (10830) / Public (10863)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined) [10830/10863]				
	Authority type: <input checked="" type="checkbox"/> Non-complex Authority Required (non-CAR)				
	Indication: Parkinson Disease				
	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 specialist unit in a hospital setting.				

- 3.3 The requested listings for Movapo POD align to the current listings for Apomine Solution for Infusion. Apomine Solution for Infusion include nurse practitioners as authorised prescribers for General Schedule maintenance therapy listings.
- 3.4 The submission stated that although Movapo POD and Apomine Solution for Infusion are bioequivalent, they are not interchangeable due to the different pump attachment mechanisms.

4 Comparator

- 4.1 The submission nominated Apomine Solution for Infusion as the main comparator. This was appropriate.

5 Consideration of the evidence

Sponsor hearing

- 5.1 There was no hearing for this item.

Consumer comments

- 5.2 The PBAC noted and welcomed the input from organisations (1) (Parkinson’s Australia Limited) via the Consumer Comments facility on the PBS website. The comment described the challenges of living with Parkinson’s disease, and that it is important to have a range of therapy options available. The comment stated that apomorphine is effective in reducing symptoms of Parkinson’s disease, improves the quality of life for patients and enables them to engage more fully in daily activities.

Clinical evidence

- 5.3 The submission stated that it did not present any clinical evidence due to the TGA considering Movapo POD to be bioequivalent to Apomine Solution for Infusion 100 mg/20 mL.

Clinical claim

- 5.4 The submission claimed non-inferior comparative effectiveness and non-inferior comparative safety of Movapo POD compared with Apomine Solution for Infusion.
- 5.5 The PBAC considered that the claim of non-inferior comparative effectiveness and safety was reasonable.

Economic analysis

- 5.6 As a Committee Secretariat submission, the economic analysis has not been independently evaluated.
- 5.7 The submission presented a cost-minimisation approach of Movapo POD compared with Apomine Solution for Infusion. The equi-effective doses were estimated as 1 mg Movapo POD = 1 mg Apomine Solution for Infusion.

- 5.8 The submission stated that, in clinical practice, it was anticipated that Movapo PFS would be replaced by Movapo POD as it is being discontinued, and has the same collar attachment to attach the syringe to the pump.
- 5.9 The submission stated there would be a cost saving to the PBS/RPBS if patients switch from using Movapo PFS to Movapo POD, because the cost for the maximum quantity of Movapo PFS is higher than the requested price for Movapo POD (the dispensed price for maximum quantity (DPMQ) for 9,000 mg of Movapo PFS under the General Schedule listing is \$8,152.59, compared to the requested DPMQ of \$ for Movapo POD 9,000 mg, under the General Schedule listing).

Drug cost/patient/year: \$ (S100 HSD Public), \$ (S100 HSD Private), \$ (General Schedule)

- 5.10 The estimated drug cost/patient per year, based on 12 prescriptions per year for the maximum quantity requested would be:
- \$ for the S100 HSD Public listing, at a DPMQ of \$
 - \$ for the S100 HSD Private listing, at a DPMQ of \$
 - \$ for the General Schedule listing, at a DPMQ of \$.

Estimated PBS usage and financial implications

- 5.11 The requested price was based on the approved ex-manufacturer price (AEMP) of Apomine Solution for Infusion listed in the PBS.
- 5.12 The submission stated it did not expect the proposed listing of Movapo POD to increase the market for apomorphine.
- 5.13 The submission used a market share approach to estimate uptake and use of Movapo POD. The current market for apomorphine was obtained from the PBS Item Report from January 2019 – December 2024, which was used to extrapolate market growth for apomorphine. Given the planned discontinuation of Movapo PFS (50 mg/10 mL), it was assumed there would be a % growth of the apomorphine 100 mg/20 mL presentation in the first year, and no further growth after this. The submission estimated Movapo POD would take up % of the apomorphine 100 mg/20 mL market, which was based on the sponsor's internal uptake estimates and market share of the Movapo brand currently.
- 5.14 Refer to Table 1 which presents the estimated extent of use, cost of Movapo POD to the PBS/RPBS and the net financial implications to the PBS/RPBS. The financial impact to Services Australia will be determined by that agency as part of the post PBAC process.
- 5.15 The submission estimated that 500 to <5,000 scripts of Movapo POD would be supplied over the first six years of listing (< 500 in Year 1 to < 500 in Year 6).

- 5.16 The submission stated that the estimated net financial impact to the PBS/RPBS for the listing of Movapo POD is \$0 to <\$10 million over six years (Year 1 \$0 to <\$10 million to Year 6 \$0 to <\$10 million), as the requested price for Movapo POD is cost-minimised to Apomine Solution for Infusion and listing Movapo POD is not expected to grow the market. The submission also claimed that if Movapo PFS is discontinued and patients currently using this form switch to Movapo POD, there would be a cost-saving to the PBS/RPBS, as the total cost for the maximum quantity is lower for Movapo POD than for Movapo PFS 50 mg/10 mL (i.e. the AEMP for Movapo PFS 50 mg/10 mL is \$0 to < \$5,000 versus \$412.63 for apomorphine 100 mg/20 mL as of June 2025).

Table 1: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of scripts dispensed	1 ¹	1 ¹	1 ¹	1 ¹	1 ¹	1 ¹
Estimated financial implications of Movapo POD						
Cost to PBS/RPBS less co-payment	\$2 ²	\$2 ²	\$2 ²	\$2 ²	\$2 ²	\$2 ²
Estimated financial implications of Apomine Solution for Infusion						
Cost to PBS/RPBS less co-payment	-\$2 ²	-\$2 ²	-\$2 ²	-\$2 ²	-\$2 ²	-\$2 ²
Net financial implications						
Net cost to PBS/RPBS	\$2 ²	\$2 ²	\$2 ²	\$2 ²	\$2 ²	\$2 ²

PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.

Source: Utilisation and Cost Model Workbook

The redacted values correspond to the following ranges:

¹ < 500

² \$0 to < \$10 million

6 PBAC Outcome

- 6.1 The PBAC recommended the listing of apomorphine (injection containing apomorphine hydrochloride hemihydrate 100 mg in 20 mL; Movapo POD) as General Schedule Authority Required (STREAMLINED) and Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listings, under the same circumstances as apomorphine hydrochloride hemihydrate 100 mg/20 mL injection currently listed on the PBS (Apomine Solution for Infusion), for the treatment of Parkinson disease.
- 6.2 The PBAC considered Apomine Solution for Infusion to be an appropriate comparator, and noted that the TGA established Movapo POD is bioequivalent to Apomine Solution for Infusion. The PBAC recommended listing Movapo POD on a cost-minimisation basis to Apomine Solution for Infusion.
- 6.3 The PBAC advised the equi-effective doses to be 1 mg Movapo POD = 1 mg Apomine Solution for Infusion.

- 6.4 The PBAC recommended a General Schedule 60-Day Maximum dispensed quantity listing for Movapo POD, to align with the current listings for Apomine Solution for Infusion.
- 6.5 The PBAC advised that Movapo POD is suitable for prescribing by nurse practitioners for the General Schedule listings.
- 6.6 The PBAC considered there would be nil financial implications as Movapo POD is recommended on a cost-minimisation basis to Apomine Solution for Infusion, and the listing of Movapo POD is not expected to grow the market.
- 6.7 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because Movapo POD is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over Apomine Solution for Infusion, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.
- 6.8 The PBAC noted that this submission is not eligible for an Independent Review because it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

7.1 Add new item:

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	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined) [codes: 10830/10863]				
	Authority type: <input checked="" type="checkbox"/> Non-complex Authority Required (non-CAR)				
Indication: Parkinson Disease					
Clinical criteria:					
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Restriction Summary 10720/ Treatment of Concept: 10844					
Concept ID (for internal Dept. use)	Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
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	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
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	Indication: Parkinson Disease				
	Treatment Phase: Maintenance therapy				
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	AND				
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These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.

8 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.

9 Sponsor's Comment

Parkinson's disease places a profound and evolving burden on patients, carers, and clinicians. The fluctuating nature of motor symptoms and their impact on daily functioning highlight the importance of having a range of effective therapeutic

options. Apomorphine has demonstrated meaningful clinical benefit in managing motor fluctuations, helping patients regain autonomy, improve quality of life, and participate more fully in everyday activities.

STADA is pleased to support the availability of apomorphine on the PBS, reaffirming our commitment to advancing patient-centred care and expanding access to therapies that make a tangible difference in the lives of those affected by Parkinson's disease.

The sponsor had no comment.