

**6.14 APOMORPHINE,  
Solution for subcutaneous infusion containing  
apomorphine hydrochloride hemihydrate 50 mg in  
10 mL pre-filled syringe,  
MOVAPO® PFS,  
STADA PHARMACEUTICALS AUSTRALIA PTY LIMITED**

**1 Purpose of Application**

- 1.1 The minor submission requested an extension to the current listing of apomorphine 50 mg in 10 mL solution for subcutaneous infusion pre-filled syringe (Movapo® PFS) for the treatment of Parkinson's disease (PD) to include General Schedule, Authority Required (STREAMLINED) listings for maintenance treatment following initiation in a hospital setting under the current Section 100 Highly Specialised Drugs (S100 HSD) Program listings.

**2 Background**

***Registration status***

- 2.1 Movapo PFS was TGA registered on 29 July 2008 under its original trade name (Apomine® PFS) with the following indication: 'to reduce the number and severity of 'off' phases in patients with PD 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'.

***Previous PBAC consideration***

- 2.2 In July 2016, the PBAC recommended the S100 HSD Authority Required listing of Movapo PFS for the treatment of PD (paragraph 5.1, Apomorphine Public Summary Document (PSD), July 2016 PBAC Meeting).
- 2.3 In March 2020, the PBAC recommended extending the listing of apomorphine 100 mg in 20 mL injection (Apomine® Solution for Infusion), 30 mg in 3 mL injection (Apomine® Intermittent) and 30 mg in 3 mL injection (Movapo® Pen) to include a General Schedule, Authority Required (STREAMLINED) listing for patients requiring maintenance treatment for PD at a price which would be cost-neutral to the Section 100 HSD listings (paragraph 5.1, Apomorphine PSD, March 2020 PBAC Meeting). In making this recommendation, the PBAC considered it was clinically appropriate for maintenance treatment with apomorphine to be prescribed outside of a hospital setting, provided treatment commenced in hospital (paragraph 5.2, Apomorphine PSD, March 2020 PBAC Meeting).

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

### 3 Requested listing

3.1 The submission requested an additional General Schedule listing to facilitate maintenance of therapy initiated in a hospital setting. Suggestions and additions proposed by the Secretariat to the requested listing are in italics and deletions in strikethrough.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. Qty packs	Max. Qty units	No. of Rpts	Dispensed Price Max. Qty	Available brands
APOMORPHINE apomorphine hydrochloride hemihydrate 50 mg/10 mL injection, 5 x 10 mL syringes	NEW (General Schedule) 10950H (Pub) 10971K (Priv)	36	180	5	\$8345.00 (Gen Sched) \$8168.04 (Pub) \$8215.74 (Priv)	Movapo PFS
apomorphine hydrochloride hemihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules	<i>NEW (General Schedule)</i> 5610G (Pub) 9640J (Priv)	36	180	5	<i>\$8168.04 (Gen Sched)</i> \$8168.04 (Pub) \$8215.74 (Priv)	Movapo
apomorphine hydrochloride hemihydrate 20 mg/2 mL injection, 5 x 2 mL ampoules	<i>NEW (General Schedule)</i> 5609F (Pub) 9607P (Priv)	72	360	5	<i>\$6528.96 (Gen Sched)</i> \$6528.96 (Pub) \$6577.02 (Priv)	Movapo

#### Restriction Summary 10720/ Treatment of Concept: 10844

<b>Category / Program:</b> GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse Practitioners - SCM
<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required – Streamlined (10844)
<b>Indication:</b> Parkinson Disease
<b>Treatment Phase:</b> <del>Continuing</del> Maintenance therapy
<b>Clinical criteria:</b>
<del>The treatment must be commenced hospital-based movement disorder clinic</del> Patient must have been commenced on treatment in a specialist unit in a hospital setting
<b>AND</b>
<b>Clinical criteria:</b>
Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy
<b>Administrative Advice:</b> <b>Shared Care Model:</b> 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.

3.2 The PBAC noted that, if it were to recommend the requested change, flow-on changes to the existing S100 listings would apply to state that treatment must be initiated in a hospital setting.

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 evidence**

4.3 The minor resubmission presented one published study, which assessed the efficacy and safety of apomorphine subcutaneous infusion in PD patients with motor complications not well controlled on medical treatment.

4.4 Details of the study presented in the submission are provided in the table below.

**Table 1: Trials and associated reports presented in the submission**

<b>Trial ID/First Author</b>	<b>Protocol title/ Publication title</b>	<b>Publication citation</b>
CT-37527-13-0124 (TOLEDO) Dr. Donna Lockhart	Multicentre, parallel-group, double blind, placebo-controlled phase III study to evaluate the efficacy and safety of apomorphine subcutaneous infusion in Parkinson's disease patients with motor complications not well controlled on medical treatment	Clinical Study Report Version 2 published: 05 Aug 2019 .

Source: Britannia Pharmaceuticals Ltd of the submission

4.5 The minor submission also reported the clinical overview (efficacy and safety) from 28 literature references and one of these (NNC APO-101<sup>1</sup>) was a sponsored study.

4.6 The PBAC considered that the clinical efficacy and safety of apomorphine had been considered previously and were not the focus of the current minor submission.

4.7 As a minor submission, no evaluation of the referenced studies was undertaken.

### **Drug cost/patient/year: \$100,140**

4.8 The estimated cost/patient per year was \$100,140 based on 12 prescriptions per year for the maximum quantity requested at a DPMQ of \$8,345.

### **Economic analysis**

4.9 The minor resubmission presented a published economic analysis, which assessed the prevalence, cost and burden of PD in Australia in order to raise awareness of the impacts of the condition and contribute to improving policy in this area.

4.10 Details of the analysis presented in the submission are provided in the table below.

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<sup>1</sup> Ostergaard L, Werdelin L, Odin P, Lindvall O, Dupont E, Christensen PB, Boisen E, Jensen NB, Ingwersen SH, Schmiegelow M. Pen injected apomorphine against off phenomena in late Parkinson's disease: a double blind, placebo controlled study. *J Neurol Neurosurg Psychiatry* 1995; **58(6)**: 681-7

**Table 2: Economic analysis presented in the submission**

Author/s	Protocol title/ Publication title	Publication citation
Deloitte Access Economics. (2015).	Living with Parkinson's Disease: An Updated Economic Analysis	Deloitte, (August 2015), 1–146.

Source: Deloitte Parkinson disease of the submission

4.11 As a minor submission, no evaluation of the referenced study was undertaken.

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

4.12 The minor submission proposed no change to the current approved ex-manufacturer price (AEMP) for this product.

4.13 The PBAC 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 also considered that the sponsor should reduce the ex-manufacturer price of the drug to ensure that the impact to government would remain cost neutral for a dual Section 100 and General Schedule listing of apomorphine (paragraph 5.6, Apomorphine PSD, March 2020 PBAC Meeting).

4.14 The minor submission used a market share approach to estimate the financial impact of the proposed General Schedule listing of Movapo PFS for maintenance therapy of PD. The PBAC considered this was appropriate.

4.15 The submission reported the additional listing of Movapo PFS on the General schedule is expected to reduce the units dispensed of the S100 HSD drugs listings of Movapo® PFS (PBS item code 10950H and 10971K) (see Table 3 and Table 4).

4.16 The submission claimed that the additional listing for Movapo® PFS was not expected to result in an increase in utilisation and the size of the market will remain the same.

4.17 The minor submission presented two estimates of the proportion of prescriptions that would transition from the existing S100 HSD listing to a new General Schedule listing. One estimate was based on the proportion of prescriptions for sirolimus that transitioned under the General Schedule listing (75.53%) after originally being listed solely under S100 HSD. The second estimate was based on the distribution of prescriptions of Duodopa® (levodopa + carbidopa) intestinal gel dispensed under the General Schedule (95.79%), noting that this product has always had a dual listing in both Section 100 and the General Schedule. The PBAC previously accepted these approaches when it recommended General Schedule listings of Apomine Intermittent and Apomine Solution for maintenance therapy of PD (paragraph 4.3, Apomorphine PSD, March 2020 PBAC Meeting).

Estimates based 75.53% uptake

4.18 The minor submission estimated a net cost to the PBS of \$124,967 in Year 6 of listing, and \$660,253 over the first six years of listing. This is summarised in Table 3.

**Table 3: Estimated financial implications based on a 75.53% uptake**

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
<b>Estimated financial implications of MOVAPO PFS</b>						
Estimated number of scripts	638	678	718	758	798	838
Cost to PBS	\$5,262,665	\$5,588,285	\$5,922,249	\$6,247,869	\$6,581,833	\$6,907,452
Less co-payments	-\$8,099	-\$8,600	-\$9,114	-\$9,615	-\$10,129	-\$10,630
Net cost to PBS	\$5,254,567	\$5,579,685	\$5,913,135	\$6,238,254	\$6,571,704	\$6,896,822
Cost to RPBS	\$58,415	\$66,760	\$66,760	\$75,105	\$75,105	\$83,450
Less co-payments	-\$46	-\$53	-\$53	-\$59	-\$59	-\$66
Net cost to RPBS	\$58,369	\$66,707	\$66,707	\$75,046	\$75,046	\$83,384
Net cost PBS / RPBS	\$5,312,936	\$5,646,392	\$5,979,843	\$6,313,299	\$6,646,750	\$6,980,206
<b>Estimated financial implications of financial impact from any affected medicine (at the published price) – Combined impact of apomorphine solution PBS items 10950H and 10971K</b>						
Cost to PBS	-\$5,168,596	-\$5,488,375	-\$5,816,369	-\$6,136,196	-\$6,464,190	-\$6,783,969
Less co-payments	\$8,099	\$8,600	\$9,114	\$9,615	\$10,129	\$10,630
Net cost to PBS	-\$5,160,497	-\$5,479,775	-\$5,807,255	-\$6,126,581	-\$6,454,061	-\$6,773,339
Cost to RPBS	-\$57,367	-\$65,583	-\$65,583	-\$73,751	-\$73,751	-\$81,967
Less co-payments	\$46	\$53	\$53	\$59	\$59	\$66
Net cost to RPBS	-\$57,321	-\$65,530	-\$65,530	-\$73,691	-\$73,691	-\$81,901
Total cost to PBS/RPBS	-\$5,217,818	-\$5,545,305	-\$5,872,785	-\$6,200,272	-\$6,527,753	-\$6,855,240
<b>Net total PBS impact of the listing of MOVAPO PFS</b>						
<b>PBS</b>						
New listing	\$5,254,567	\$5,579,685	\$5,913,135	\$6,238,254	\$6,571,704	\$6,896,822
Changed listing	-\$5,160,497	-\$5,479,775	-\$5,807,255	-\$6,126,581	-\$6,454,061	-\$6,773,339
Net cost to PBS	\$94,070	\$99,910	\$105,880	\$111,673	\$117,643	\$123,483
<b>RPBS</b>						
New listing	\$58,369	\$66,707	\$66,707	\$75,046	\$75,046	\$83,384
Changed listing	-\$57,321	-\$65,530	-\$65,530	-\$73,691	-\$73,691	-\$81,901
Net cost to RPBS	\$1,048	\$1,177	\$1,177	\$1,354	\$1,354	\$1,483
Net cost PBS / RPBS	\$95,118	\$101,087	\$107,057	\$113,027	\$118,997	\$124,967
<b>Cost changes of MBS items based on 75.53% uptake</b>						
Increased cost	\$19,486	\$20,709	\$21,932	\$23,155	\$24,378	\$25,601
Decreased cost	-\$45,680	-\$48,547	-\$51,414	-\$54,281	-\$57,148	-\$60,015
Net cost to MBS	-\$26,194	-\$27,838	-\$29,482	-\$31,126	-\$32,770	-\$34,414
<b>Net cost to Health budget with an uptake of 75.53%</b>						

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	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Net Cost to PBS/RPBS	\$95,118	\$101,087	\$107,057	\$113,027	\$118,997	\$124,967
Net Cost to MBS	-\$26,194	-\$27,838	-\$29,482	-\$31,126	-\$32,770	-\$34,414
Net cost to Health Budget	\$68,924	\$73,249	\$77,575	\$81,901	\$86,227	\$90,553

Source: Table 4.4, 4.6, 4.8, 4.10, 4.12, 4.14 of the submission

Estimates based 95.79% uptake

4.19 The minor submission estimated a net cost to the PBS of \$156,698 and \$827,669 over the first six years of listing. This is summarised in Table 4.

**Table 4: Estimated financial implications based on 95.79% uptake**

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
<b>Estimated financial implications of MOVAPO PFS</b>						
Estimated number of scripts	809	859	910	961	1,012	1,062
Cost to PBS	\$6,673,290	\$7,088,492	\$7,512,038	\$7,918,894	\$8,342,440	\$8,765,986
Less co-payments	-\$10,270	-\$10,908	-\$11,560	-\$12,186	-\$12,838	-\$13,490
Net cost to PBS	\$6,663,021	\$7,077,583	\$7,500,477	\$7,906,708	\$8,329,602	\$8,752,496
Cost to RPBS	\$75,105	\$83,450	\$83,450	\$100,140	\$100,140	\$100,140
Less co-payments	-\$59	-\$66	-\$66	-\$79	-\$79	-\$79
Net cost to RPBS	\$75,046	\$83,384	\$83,384	\$100,061	\$100,061	\$100,061
Net cost PBS/ RPBS	\$6,738,066	\$7,160,967	\$7,583,861	\$8,006,768	\$8,429,663	\$8,852,557
<b>Estimated financial implications of financial impact from any affected medicine (at the published price) – Combined impact of Apomorphine solution PBS items 10950H and 10971K</b>						
Cost to PBS	-\$6,554,013	-\$6,961,772	-\$7,377,747	-\$7,777,338	-\$8,193,314	-\$8,609,289
Less co-payments	\$10,270	\$10,908	\$11,560	\$12,186	\$12,838	\$13,490
Net cost to PBS	-\$6,543,743	-\$6,950,864	-\$7,366,187	-\$7,765,152	-\$8,180,475	-\$8,595,799
Cost to RPBS	-\$73,751	-\$81,967	-\$81,967	-\$98,350	-\$98,350	-\$98,350
Less co-payments	\$59	\$66	\$66	\$79	\$79	\$79
Net cost to RPBS	-\$73,691	-\$81,901	-\$81,901	-\$98,271	-\$98,271	-\$98,271
Total cost to PBS/RPBS	-\$6,617,435	-\$7,032,764	-\$7,448,087	-\$7,863,423	-\$8,278,747	-\$8,694,070
<b>Net total PBS impact of the listing of MOVAPO PFS</b>						
<b>PBS</b>						
New listing	\$6,663,021	\$7,077,583	\$7,500,477	\$7,906,708	\$8,329,602	\$8,752,496
Changed listing	-\$6,543,743	-\$6,950,864	-\$7,366,187	-\$7,765,152	-\$8,180,475	-\$8,595,799
Net cost to PBS	\$119,278	\$126,719	\$134,291	\$141,556	\$149,127	\$156,698
<b>RPBS</b>						
New listing	\$75,046	\$83,384	\$83,384	\$100,061	\$100,061	\$100,061

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Changed listing	-\$73,691	-\$81,901	-\$81,901	-\$98,271	-\$98,271	-\$98,271
Net cost to RPBS	\$1,354	\$1,483	\$1,483	\$1,790	\$1,790	\$1,790
Net cost PBS / RPBS	\$120,632	\$128,203	\$135,774	\$143,345	\$150,916	\$158,487
<b>Cost changes of MBS items based on 95.79% uptake</b>						
Increased cost	\$24,713	\$26,264	\$27,815	\$29,366	\$30,917	\$32,468
Decreased cost	-\$57,933	-\$61,570	-\$65,206	-\$68,842	-\$72,478	-\$76,114
Net cost to MBS	-\$33,220	-\$35,305	-\$37,390	-\$39,475	-\$41,560	-\$43,645
<b>Net cost to Health budget with an uptake of 95.79%</b>						
Net Cost to PBS/RPBS	\$120,632	\$128,203	\$135,774	\$143,345	\$150,916	\$158,487
Net Cost to MBS	-\$33,220	-\$35,305	-\$37,390	-\$39,475	-\$41,560	-\$43,645
Net cost to Health Budget	\$87,412	\$92,898	\$98,384	\$103,870	\$109,356	\$114,842

Source: Table 4.5, 4.7, 4.9, 4.11, 4.13, 4.15 of the submission

4.20 The utilisation estimates in the submission were based on the 2019 calendar year.

4.21 As a minor submission, the financial estimates were not independently evaluated.

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

## 5 PBAC Outcome

5.1 The PBAC recommended an extension to the current listing of apomorphine 50 mg in 10 mL solution for subcutaneous infusion pre-filled syringe (Movapo® PFS) for the treatment of PD to include General Schedule Authority Required (STREAMLINED) listings for maintenance therapy only following initiation in a hospital setting under the current Section 100 Highly Specialised Drugs (S100 HSD) Program listings.

5.2 The PBAC noted that this recommendation was consistent with its previous advice that it was clinically appropriate for maintenance treatment with apomorphine to be prescribed outside of a hospital setting, provided treatment commenced in hospital (paragraph 5.2, Apomorphine PSD, March 2020 PBAC Meeting).

5.3 The PBAC noted that a General Schedule listing for maintenance therapy would allow patients with PD access to apomorphine through a community pharmacy and prescribed via a General Practitioner or Nurse Practitioner.

5.4 The PBAC recalled its previous advice that, for a dual Section 100 and General Schedule listing, the sponsor should reduce the AEMP of the drug to ensure that the impact to government remained cost neutral (paragraph 5.6, Apomorphine PSD, March 2020 PBAC Meeting). The PBAC therefore considered that the sponsor should reduce the AEMP of apomorphine 50 mg in 10 mL solution for subcutaneous infusion pre-filled syringe (Movapo PFS) accordingly.

- 5.5 The PBAC recommended that, to ensure consistency across all of the apomorphine items on the PBS, it would be reasonable for the current listings of apomorphine 20 mg/2 mL and 50 mg/5 mL ampoules (Movapo®) to also be extended to include General Schedule, Authority Required (STREAMLINED) listings for maintenance therapy, and that the AEMPs for these listings should be reduced as outlined in paragraph 5.4.
- 5.6 The PBAC noted that, as a result of this recommendation, flow-on changes to the existing S100 listings for apomorphine 50 mg in 10 mL solution for subcutaneous infusion pre-filled syringe (Movapo PFS), 20 mg/2 mL ampoules (Movapo) and 50 mg/5 mL ampoules (Movapo) would apply to state that treatment must be initiated in a hospital setting.
- 5.7 The PBAC reiterated its previous advice 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 (Paragraph 5.7, Apomorphine PSD, March 2020 PBAC Meeting).
- 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 found that the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* for Pricing Pathway A were not met. Specifically the PBAC found that in the circumstances of its recommendation for apomorphine:
- a) The treatment is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over alternative therapies, because apomorphine is already PBS listed;
  - b) The treatment is not expected to address a high and urgent unmet clinical need because it is already PBS listed and other forms are available on the General Schedule
  - c) It was not necessary to make a finding in relation to whether it would be in the public interest for the subsequent pricing application to be progressed under Pricing Pathway A because one or more of the preceding tests had failed
- 5.10 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 Add a new General Schedule listing for the following products as follows:

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. Qty packs	Max. Qty units	No. of Rpts	Available brands
APOMORPHINE					
apomorphine hydrochloride hemihydrate 50 mg/10 mL injection, 5 x 10 mL syringes	NEW	36	180	5	Movapo PFS
apomorphine hydrochloride hemihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules	NEW	36	180	5	Movapo
apomorphine hydrochloride hemihydrate 20 mg/2 mL injection, 5 x 2 mL ampoules	NEW	72	360	5	Movapo
<b>Attach Restriction Summary 10720 / Treatment of Concept: 10844 to the existing 3 medicinal product packs listed above:</b>					
	<b>Category / Program:</b> GENERAL – General Schedule (Code GE)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse Practitioners - SCM				
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required – Streamlined (10844)				
	<b>Administrative Advice:</b> <b>Shared Care Model:</b> 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.				
	<b>Indication:</b> Parkinson Disease				
	<b>Treatment Phase:</b> Maintenance therapy				
	<b>Clinical criteria:</b>				
	Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
	Patient must have been commenced on treatment in a specialist unit in a hospital setting				

- 6.2 Flow-on changes to the existing Section 100 (HSDP) listings to stipulate that treatment must be initiated in a hospital setting, are outlined as follows:

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. Qty packs	Max. Qty units	№.of Rpts	Available brands
APOMORPHINE					
apomorphine hydrochloride hemihydrate 50 mg/10 mL injection, 5 x 10 mL syringes	10950H (Pub)	36	180	5	Movapo PFS
apomorphine hydrochloride hemihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules	5610G (Pub)	36	180	5	Movapo
apomorphine hydrochloride hemihydrate 20 mg/2 mL injection, 5 x 2 mL ampoules	5609F (Pub)	72	360	5	Movapo
<b>Amend Restriction Summary 4833 / Treatment of Concept: 4833</b>					
	<b>Category / Program:</b> S100 – Section 100 (Highly Specialised Drugs) – Public hospitals (Code HB)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners				
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required – Streamlined (4833)				
	<b>Indication:</b> Parkinson Disease				
	<b>Clinical criteria:</b>				
	Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
	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	№.of Rpts	Available brands
APOMORPHINE					
apomorphine hydrochloride hemihydrate 50 mg/10 mL injection, 5 x 10 mL syringes	10971K (Priv)	36	180	5	Movapo PFS
apomorphine hydrochloride hemihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules	9640J (Priv)	36	180	5	Movapo
apomorphine hydrochloride hemihydrate 20 mg/2 mL injection, 5 x 2 mL ampoules	9607P (Priv)	72	360	5	Movapo
<b>Amend Restriction Summary 9561 / Treatment of Concept :9561</b>					
	<b>Category / Program:</b> S100 – Section 100 (Highly Specialised Drugs) – Private hospitals (Code HS)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners				
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required – Streamlined (9561)				
	<b>Indication:</b> Parkinson Disease				
	<b>Clinical criteria:</b>				
	Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
	Patient must have been commenced on treatment in a specialist unit in a hospital setting				

**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.