

6.13 LEVODOPA WITH CARBIDOPA

Intestinal gel containing levodopa 20 mg with carbidopa monohydrate 5 mg per mL, 100 mL Duodopa[®], AbbVie Pty Ltd

1 Purpose of Application

- 1.1 To request additional General Schedule and Section 100 (Highly Specialised Drugs (HSD) Program) Authority Required (STREAMLINED) listings with a different maximum quantity, and amend the current listings, for levodopa with carbidopa monohydrate intestinal gel (Duodopa[®]) for the treatment of advanced Parkinson's disease.

2 Requested listing

- 2.1 The submission proposed new listings that were identical to current listings with the exception of a reduced maximum quantity of 4 packs (compared with 8 packs for the current listings); and to change all current listings to add an additional clinical criteria.
- 2.2 Suggestions and additions proposed by the Secretariat to the requested listing are in italics and deletions are in strikethrough.

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New listings

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty ^a	Proprietary Name and Manufacturer
LEVODOPA WITH CARBIDOPA levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL	4	5	<i>GE</i> \$5,920.11 (<i>Published</i>) \$ [REDACTED] (<i>Effective</i>) <i>HSD (Public)</i> \$5,768.00 (<i>Published</i>) \$ [REDACTED] (<i>Effective</i>) <i>HSD (Private)</i> \$5,815.39 (<i>Published</i>) \$ [REDACTED] (<i>Effective</i>)	Duodopa® AbbVie Pty Ltd

^a Calculated during the minor overview based on the current AEMP (published \$1,442, effective \$ [REDACTED], 1 October 2019).

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
PBS Indication:	Advanced Parkinson disease
Treatment phase:	Maintenance therapy
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – In Writing <input type="checkbox"/> Authority Required – Telephone/Electronic/Emergency <input checked="" type="checkbox"/> Streamlined
Clinical criteria:	Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, AND Patient must have been commenced on treatment in a hospital-based movement disorder clinic.
Administrative Advice:	Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump. 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. Special Pricing Arrangements apply.

Category / Program:	Section 100 – Highly Specialised Drugs Program (Public and 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
PBS Indication:	Advanced Parkinson disease
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – In Writing <input type="checkbox"/> Authority Required – Telephone/Electronic/Emergency <input checked="" type="checkbox"/> Streamlined
Clinical criteria:	Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, AND The treatment must be commenced in a hospital-based movement disorder clinic.

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Administrative Advice:	<p>Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.</p> <p>Special Pricing Arrangements apply.</p>
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Current listings

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
LEVODOPA WITH CARBIDOPA levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL	8	5	GE \$11,688.11 (Published) \$ [REDACTED] (Effective) HSD \$11,536.00 (Published) (Public) \$ [REDACTED] (Effective) HSD \$11,583.39 (Published) (Private) \$ [REDACTED] (Effective)	Duodopa® AbbVie 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
PBS Indication:	Advanced Parkinson disease
Treatment phase:	Maintenance therapy
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – In Writing <input type="checkbox"/> Authority Required – Telephone/Electronic/Emergency <input checked="" type="checkbox"/> Streamlined
Clinical criteria:	<p>Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, AND Patient must have been commenced on treatment in a hospital-based movement disorder clinic, AND Patient must require continuous administration without an overnight break or a total dose per day of levodopa > 2000 mg. Patient must require continuous administration without an overnight break or a total dose of more than 2000 mg of levodopa per day.</p>
Administrative Advice:	<p>Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.</p> <p>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.</p> <p>Special Pricing Arrangements apply.</p>

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Category / Program:	Section 100 – Highly Specialised Drugs Program (Public and 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
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Administrative Advice:	Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump. Special Pricing Arrangements apply.

3 Background

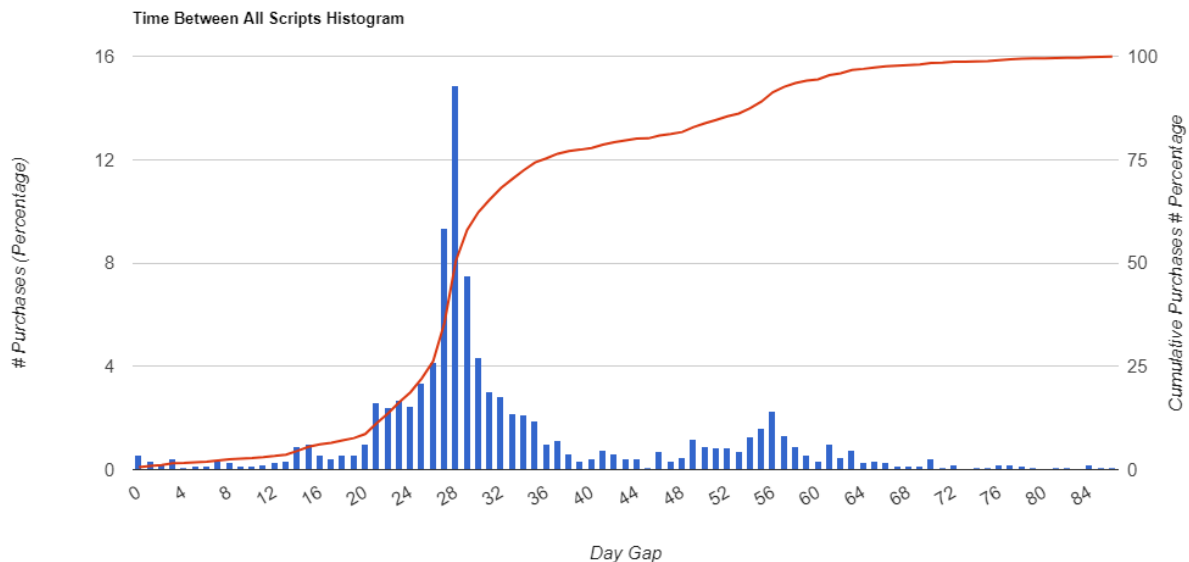
- 3.1 Duodopa was registered by the TGA on the 27 February 2008 for the treatment of advanced idiopathic Parkinson’s disease with severe motor fluctuations despite optimised alternative pharmacological treatment.
- 3.2 In November 2010, the PBAC recommended the Section 100 (HSD Program) listing of Duodopa for the management of advanced Parkinson disease in a patient with severe disabling motor fluctuations not adequately controlled by oral therapy, and on the General Schedule for maintenance therapy (Levodopa with carbidopa, Public Summary Document (PSD), November 2010 PBAC meeting).

4 Current situation

- 4.1 The minor submission stated the requested listings with a reduced maximum quantity are intended to ensure appropriate use of Duodopa within the registered shelf-life of thawed product.
- 4.2 The minor submission stated that the majority of patients treated with Duodopa are infused with up to one single-use cassette per day, with an overnight break and therefore require only 4 packs every 28 days. If medically justified, some patients require more than one cassette per day (or more than four cassettes every 28 days). These patients may require a higher dose (more than 2000mg, or 1 cassette per day) through the day, or continuous administration without an overnight break (4000mg, or 2 cassettes per day).

4.3 The minor submission demonstrated there is a potential quality use of medicines (QUM) issue associated with some patients who require only one cassette per day using levodopa with carbidopa intestinal gel beyond the shelf-life due to dispensing every two months. International shipping and distribution practices, and the limited shelf-life of thawed product, meant the average shelf-life upon distribution to Australian pharmacies was 50 days in 2019. However, approximately 40% of patients are dispensed 8 packs every two months (defined as an average of ≤ 0.75 scripts per month) with a mean refill time of 49 days, suggesting many patients may be self-administering the product beyond the registered shelf-life. Figure 1 from the minor submission shows percentages of all Duodopa scripts by average time between refills based on a 10% PBS sample dataset.

Figure 1: Average time between all filled levodopa with carbidopa monohydrate intestinal gel scripts over the period January 2017 – February 2019 based on 10% PBS data



Source: Figure 1 of the submission

For more detail on PBAC’s view, see section 6 PBAC outcome.

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item as it was a minor submission.

Consumer comments

5.2 The PBAC noted that no consumer comments were received for this item.

Estimated PBS usage & financial implications

5.3 The minor submission did not present estimates of utilisation or financial implications.

- 5.4 Net costs to the PBS is expected to increase due to dispensing, administration and handling fees, less increased patient contributions associated with the reduced maximum quantity, but increased frequency of dispensing.
- 5.5 Duodopa is currently subject to a Deed of Agreement which encompasses a Special Pricing Arrangement (SPA) rebate and a Risk Sharing Arrangement (RSA) with subsidisation caps.

For more detail on PBAC's view, see section 6 PBAC outcome.

6 PBAC Outcome

- 6.1 The PBAC recommended to amend the current listings for levodopa with carbidopa monohydrate intestinal gel (Duodopa®) for the treatment of advanced Parkinson's disease with a maximum quantity of 8 packs to restrict access to patients requiring more than 1 cassette per day. The PBAC also recommended new Authority Required (STREAMLINED) listings for Duodopa, with a reduced maximum quantity of 4 packs, under special arrangements under Section 100 (Highly Specialised Drugs (HSD) Program) and as maintenance therapy on the General Schedule.
- 6.2 The PBAC noted there are potential QUM issues with the current listings, where some patients may be using the product beyond the registered shelf-life. It considered the new listings and changes to current listings to be appropriate measures to mitigate the risk of patients inadvertently self-administering out-of-date medicine, whilst also ensuring access for patients requiring a dose of more than 1 cassette per day regardless of if they do, or do not, have an overnight break.
- 6.3 The PBAC noted the new listings would have the same restriction wording as the current listings, and would provide 28 days' worth of treatment for patients requiring up to one cassette per day.
- 6.4 The PBAC noted that the recommended changes may result in a small net cost to the PBS due to increased frequency of dispensing. The PBAC advised the new listings should be included in the current RSA for Duodopa.
- 6.5 The PBAC advised that Duodopa is suitable for prescribing by nurse practitioners on the General Schedule, in line with the existing General Schedule listing which allows prescribing by nurse practitioners within a shared care model.
- 6.6 The PBAC advised that the Early Supply Rule should not apply to the new listings in line with the current PBS listings for Duodopa.
- 6.7 The PBAC noted that this submission is not eligible for an Independent Review because it received a positive recommendation.
- 6.8 The PBAC advised that, because listing Duodopa with reduced maximum quantities is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over current listings of Duodopa, or address a high and urgent

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unmet clinical need, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* for Pricing Pathway A were not met.

Outcome:

Recommended

7 Recommended listing

7.1 Add new items:

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Category / Program:	Section 100 – Highly Specialised Drugs Program (Public and Private Hospital)
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Administrative Advice:	Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump. Special Pricing Arrangements apply.

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

7.2 Amend existing listings for 8970D, 9743T and 9744W as follows (with additions in italics, deletions in strikethrough):

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
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Administrative Advice:	<p>Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.</p> <p>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.</p> <p>Special Pricing Arrangements apply.</p>
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Administrative Advice:	<p>Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.</p> <p>Special Pricing Arrangements apply.</p>

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

The sponsor had no comment.