

6.08 LEVODOPA WITH CARBIDOPA

Intestinal gel containing levodopa 20 mg with carbidopa (as monohydrate) 5 mg in 1 mL, 7

**Duodopa[®],
Abbvie Pty Ltd.**

1 Purpose of Application

- 1.1 The minor submission requested a change in the Note section of the current Authority Required (STREAMLINED) restriction to remove the current wording 'a positive clinical response to Duodopa[®] administered via a temporary nasoduodenal tube should be confirmed before a permanent percutaneous endoscopic gastrostomy (PEG) tube is inserted'.

2 Requested listing

- 2.1 The submission requested the following changes to the existing restriction:

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Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
LEVODOPA WITH CARBIDOPA Intestinal gel containing levodopa 20 mg/mL with carbidopa (as monohydrate) 5 mg/mL in 100 mL, 7	8	5	\$11,683.90	Duodopa®	Abbvie Pty Ltd

Category / Program	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
Condition:	Advanced Parkinson disease
PBS Indication:	Advanced Parkinson disease
Treatment Phase	Maintenance therapy
Restriction Level / Method:	<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	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. Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump

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Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
LEVODOPA WITH CARBIDOPA Intestinal gel containing levodopa 20 mg/mL with carbidopa (as monohydrate) 5 mg/mL in 100 mL, 7	8	5	Public: \$11,536.00 Private: \$11,583.02	Duodopa®	Abbvie 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:	Advanced Parkinson disease
PBS Indication:	Advanced Parkinson disease
Restriction Level / Method:	<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.

- 2.2 The PBAC considered that the request was reasonable, as the choice regarding whether to use a temporary nasoduodenal tube before inserting a permanent PEG was a clinical practice decision.

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

3 Background

- 3.1 Duodopa® was TGA registered on 27 February 2008 for the treatment of advanced idiopathic Parkinson's disease with severe motor fluctuations despite optimised oral treatment. A positive clinical response to Duodopa® administered via a temporary nasoduodenal tube should be confirmed before a permanent PEG tube is inserted.
- 3.2 Duodopa®'s PI was updated in October 2014. The stipulation of a temporary nasoduodenal tube before the insertion of a permanent PEG tube was rephrased. The current wording is as following:
"A temporary nasoduodenal/nasojejunal tube should be considered to determine if the patient responds favourably to this method of treatment before a permanent percutaneous endoscopic gastrostomy with jejunal (PEG-J) is placed. In cases where a physician considers this assessment is not necessary, the nasojejunal test phase

may be waived and treatment initiated directly with placement of the PEG-J”.

4 Comparator

4.1 As a minor submission, there was no economic comparison.

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.

Clinical trials

5.3 As a minor submission, no clinical trials were presented in the submission.

Estimated PBS usage & financial implications

5.4 The PBAC considered that there would be no financial implications associated with the change to the restriction note.

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

6 PBAC Outcome

6.1 The PBAC recommended the removal of the current wording ‘a positive clinical response to Duodopa® administered via a temporary nasoduodenal tube should be confirmed before a permanent percutaneous endoscopic gastrostomy (PEG) tube is inserted’ from the Note section under the restriction of levodopa with carbidopa on the basis that this is a clinical practice decision.

6.2 The PBAC noted the update to the PI for Duodopa® and considered that the nasojejunal test phase may be exempted under the discretion of a physician. In this situation, it is appropriate to initiate the treatment directly with placement of the PEG-J.

6.3 The PBAC considered that there would be no financial implications as a result of this listing as it will not alter utilisation.

6.4 The PBAC advised that the current arrangements for prescribing by nurse practitioners for levodopa with carbidopa should remain.

6.5 The PBAC noted that this submission is not eligible for an Independent Review as it

has received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

Amend existing/recommended listing as follows:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
LEVODOPA WITH CARBIDOPA Intestinal gel containing levodopa 20 mg/mL with 8 carbidopa (as monohydrate) 5 mg/mL in 100 mL, 7	8	5	Duodopa®	Abbvie Pty Ltd

Category / Program	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
Condition:	Advanced Parkinson disease
PBS Indication:	Advanced Parkinson disease
Treatment Phase	Maintenance therapy
Restriction Level / Method:	<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	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. Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump

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Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Manufacturer	Name and
LEVODOPA WITH CARBIDOPA Intestinal gel containing levodopa 20 mg/mL 8 with carbidopa (as monohydrate) 5 mg/mL in 100 mL, 7		5	Duodopa®	Abbvie 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:	Advanced Parkinson disease
PBS Indication:	Advanced Parkinson disease
Restriction Level / Method:	<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.

8 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.

9 Sponsor's Comment

AbbVie welcomes the decision of the PBAC.