

6.13 OCTREOTIDE

Injection (modified release) 10 mg (as acetate), vial and diluent syringe

Injection (modified release) 20 mg (as acetate), vial and diluent syringe

Injection (modified release) 30 mg (as acetate), vial and diluent syringe,

Sandostatin[®] LAR[®], Novartis Pharmaceuticals Australia Pty Ltd

1 Purpose of Application

- 1.1 The submission requested to extend the current listing for octreotide modified release injections, 10 mg/2 mL, 20 mg/2 mL and 30 mg /2 mL, to a Section 100 Highly Specialised Drug Program (HSD) Community Access, Authority Required (STREAMLINED) for patients with functional carcinoid tumours, acromegaly and vasoactive intestinal peptide secreting tumours (VIPomas).

2 Requested listing

- 2.1 The proposed Community Access PBS listings for functional carcinoid tumours, acromegaly and VIPomas applied similar treatment, clinical and population criteria to the existing Section 100 HSD Public and Private Hospital listings.

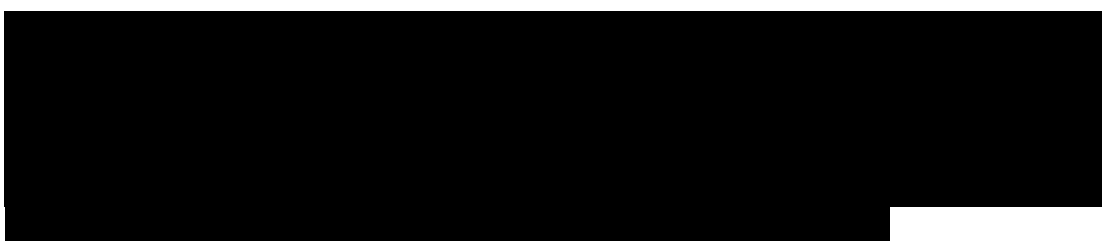
For more detail on PBAC's view, see section 6 PBAC outcome.

3 Background

- 3.1 Octreotide modified release injection is TGA registered for the treatment of;
- the symptomatic control and reduction of growth hormone and IGF-1 plasma levels in patients with acromegaly, including those who are inadequately controlled by surgery, radiotherapy, or dopamine agonist treatment but who are adequately controlled on subcutaneous treatment with Sandostatin[®]. Sandostatin[®] LAR[®] is also indicated in acromegalic patients unfit or unwilling to undergo surgery, or in the interim period until radiotherapy becomes fully effective;
 - symptoms associated with carcinoid tumours with features of the carcinoid syndrome; and

- symptoms of vasoactive intestinal peptide secreting tumours (VIPomas) in patients who are adequately controlled on subcutaneous treatment with octreotide.
- 3.2 Octreotide immediate release injection is PBS listed for patients with acromegaly, carcinoid syndrome or vasoactive intestinal peptide secreting tumour.
- 3.3 Octreotide modified release injection is PBS listed for patients with acromegaly and carcinoid tumour or vasoactive intestinal peptide secreting tumour who are controlled on octreotide immediate release injection.
- 3.4 The HSD community access arrangements, introduced on 1 July 2015, allow authorised community based practitioners to prescribe clozapine for the treatment of schizophrenia (maintenance therapy only), HIV antiretroviral treatments, and hepatitis B medicines without the need to be affiliated with a hospital. In comparison to Section 100 HSD Public and Private Hospital listings, community access arrangements remove the requirement for;
- prescribers to demonstrate a link to a hospital setting;
 - private hospital prescribers to obtain phone authority, replacing the current authority requirements with streamlined authority; and
 - patients receiving care at/or from a hospital.
- 3.5 At the November 2017 PBAC meeting the PBAC recommended extending the listing of lanreotide acetate (Somatuline® Autogel®), another somatostatin analogue with a similar patient population, to Section 100 HSD Community Access for the continuing phase of treatment. The PBAC recommended that the initial phase of treatment should remain unchanged under Section 100 HSD Public and Private Hospitals.

Committee-In-Confidence information



End of Committee-In-Confidence information

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

4 Current Situation

- 4.1 The submission argued that a Section 100 HSD Community Access listing would facilitate access for public hospital patients, particularly those living in rural and remote areas, who might be a long way from their primary treatment centre. In support of its argument, the submission referred to results of a survey of Australian patients living with neuroendocrine tumours (NETs)¹ which indicated that travelling to and from medical appointments contributed significantly to the negative impact of having a NET.
- 4.2 The Sponsor stated it supports the Sandostatin Home Injection Nurse Education Service (SHINE) program, which provides patients with a home nurse visit to administer injections. The submission stated “people prescribed Sandostatin® LAR generally attend a hospital clinic for monthly injections. However, once a patient’s condition is stable, a home visit by a nurse is more convenient than attending a hospital clinic for many patients. This is particularly the case for patients that may live remote from their treating clinic. The SHINE program currently provides assistance for [REDACTED] patients per month across Australia. Feedback from the nurses that administer this program suggests that providing easier access to Sandostatin® LAR for rural, remote and metropolitan patients would facilitate their ongoing treatment”.

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 estimated there might be a small-cost saving due to a move to an Authority Required (Streamlined) listing compared to an Authority Required telephone approval for private hospital patients. The submission did not present any estimates of the cost saving or how many patients this would affect.

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

¹ Leyden J, Pavlakis N, Chan D et al. Patient-reported experience of the impact and burden of neuroendocrine tumors: Oceania patient results from a large Global survey. *Asia-Pac J Clin Oncol* 2017; 1-8

6 PBAC Outcome

- 6.1 The PBAC recommended to extend the current listings for octreotide modified release injection 10 mg, 20 mg, 30 mg (as acetate), vial and diluent syringe from Section 100 Highly Specialised Drugs program (HSD) to Section 100 HSD Community Access, Authority Required (STREAMLINED) for the treatment of acromegaly and the symptomatic treatment of carcinoid tumours and vasoactive intestinal peptide secreting tumours (VIPomas) under the conditions noted below.
- 6.2 The PBAC recommended that the continuing phase of treatment should be available under Section 100 - HSD program (Community Access), whilst the initial phase of treatment should remain unchanged under Section 100 – HSD program (Public and Private Hospitals).
- 6.3 The PBAC noted that the Department are currently reviewing broader PBS access issues and authority listing inconsistencies within the S100 HSD program.
- 6.4 The PBAC recommended that this extension of listing be incorporated into the Department’s current work within this area. PBAC requested the Department liaise with the sponsor in order to facilitate an appropriate way to improve access to PBS listed medicines for patients living in rural and remote Australia.

Outcome:

Recommended

7 Recommended listing

- 7.1 Amend existing listing as follows:

Name, Restriction, Manner of administration and form	Max qty packs	Max qty units	No. of repeats	Proprietary Name and Manufacturer
OCTREOTIDE				
Octreotide 30 mg injection: modified release [1 vial] (& inert substance diluent [2 mL syringe], 1 pack	2	2	5	Sandostatin® Novartis LAR®
Octreotide 20 mg injection: modified release [1 vial] (& inert substance diluent [2 mL syringe], 1 pack				
Octreotide 10 mg injection: modified release [1 vial] (& inert substance diluent [2 mL syringe], 1 pack				

Category / Program:	Section 100 – Highly Specialised Drugs Program (<i>Community Access</i>)
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:	Acromegaly

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Restriction level / Method:	<input checked="" type="checkbox"/> Streamlined
Clinical criteria:	<p><i>Patient must have previously received PBS-subsidised treatment with this drug for this condition,</i></p> <p>AND</p> <p>The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose),</p> <p>AND</p> <p>The treatment must cease if IGF1 is not lower after 3 months of treatment,</p> <p>AND</p> <p>The treatment must not be given concomitantly with PBS-subsidised pegvisomant</p>
Prescriber instructions:	In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

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Octreotide 20 mg injection: modified release [1 vial] (& inert substance diluent [2 mL syringe], 1 pack				
Octreotide 10 mg injection: modified release [1 vial] (& inert substance diluent [2 mL syringe], 1 pack				

Category / Program:	Section 100 – Highly Specialised Drugs Program (<i>Community Access</i>)
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:	Functional carcinoid tumour
Restriction level / Method:	<input checked="" type="checkbox"/> Streamlined
Clinical criteria:	<p><i>Patient must have previously received PBS-subsidised treatment with this drug for this condition,</i></p> <p>AND</p> <p>The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.</p>
Prescriber instructions:	Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

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Octreotide 10 mg injection: modified release [1 vial] (& inert substance diluent [2 mL syringe], 1 pack				

Category / Program:	Section 100 – Highly Specialised Drugs Program (<i>Community Access</i>)
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:	Vasoactive intestinal peptide secreting tumour (VIPoma)
Restriction level / Method:	<input checked="" type="checkbox"/> Streamlined
Clinical criteria:	<i>Patient must have previously received PBS-subsidised treatment with this drug for this condition,</i> AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.
Prescriber instructions:	Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

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

Novartis is pleased with this outcome.