

6.17 LANREOTIDE

Solution for injection 60 mg/0.5 ml, 0.5 ml pre-filled syringe

Solution for injection 90 mg/0.5 ml, 0.5 ml pre-filled syringe

Solution for injection 120 mg/0.5 ml, 0.5 ml pre-filled syringe

Somatuline® Autogel®, Ipsen Pty Ltd

1 Purpose of Application

- 1.1 The submission sought to extend the current listing for lanreotide acetate pre-filled syringe, 120 mg/ 0.5 ml, 90 mg/ 0.5 ml and 60 mg/ 0.5 ml to a Section 100 Highly Specialised Drugs Program Community Access, Authority Required (STREAMLINED) for patients with acromegaly and functional carcinoid tumour.

2 Requested listing

- 2.1 The requested listing for acromegaly and functional carcinoid tumour is provided below. Suggestions and additions proposed by the Secretariat to the requested listing are added in italics and suggested deletions are crossed out in strikethrough.

Public Summary Document - November 2017 PBAC Meeting

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
LANREOTIDE	2	5	List price	Somatuline® Ipsen Pty Ltd
Injection, 120 mg/0.5 ml syringe			\$4,302.93	Autogel®
Injection, 90 mg/0.5 ml syringe			\$3,448.15	
Injection, 60 mg/0.5 ml syringe			\$2,602.65	
Category / Program	Section 100 – Highly Specialised Drugs Program (Community Access)			
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			
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required - Emergency <input type="checkbox"/> Authority Required - Electronic <input checked="" type="checkbox"/> Streamlined			
Treatment phase	Continuing treatment			
Treatment criteria:	In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission			
Clinical criteria:	Patient must have previously been issued with authority prescription for this drug for this condition, <i>through a Section 100 Highly Specialised Drugs Program- (Public or Private Hospitals).</i> AND The condition must be active AND Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, AND The treatment must be after failure of other therapy including dopamine agonists; OR The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated AND The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), AND The treatment must cease if IGF1 is not lower after 3 months of treatment. <i>The treatment must not be given concomitantly with PBS- subsidised pegvisomant.</i>			
Population criteria:	Patient must be aged 18 years or older			
Administrative Advice	No increase in maximum quantity or number of repeats may be authorised.			

Name, Restriction, Manner of administration and form	Max. Qty	Nr. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
LANREOTIDE ACETATE Injection, 120 mg/0.5 ml syringe Injection, 90 mg/0.5 ml syringe Injection, 60 mg/0.5 ml syringe	2	5	List price \$4,302.93 \$3,448.15 \$2,602.65	Somatuline® Ipsen Pty Ltd Autogel®
Category / Program	Section 100 – Highly Specialised Drugs Program (Community Access)			
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 type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required - Emergency <input type="checkbox"/> Authority Required - Electronic <input checked="" type="checkbox"/> Streamlined			
Treatment phase	Continuing treatment			
Treatment criteria:	Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.			
Clinical criteria:	Patient must have previously been issued with authority prescription for this drug for this condition, <i>through a Section 100 Highly Specialised Drugs Program- (Public or Private Hospitals)</i> . AND The condition must be causing intractable symptoms, AND Patients must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents AND Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate 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 120 mg every 28 days			
Population criteria:	Patient must be aged 18 years or older			
Administrative Advice	No increase in maximum quantity or number of repeats may be authorised.			

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

3 Background

- 3.1 Lanreotide is TGA registered for the treatment of acromegaly when the circulating levels of growth hormone and insulin-like growth factor 1 (IGF-1) remain abnormal after surgery and/or radiotherapy or in patients who are dopamine agonist treatment refractory; symptoms of carcinoid syndrome associated with carcinoid tumours; and Gastroenteropancreatic Neuroendocrine Tumours (GEP-NETs) in adult patients with unresectable locally advanced or metastatic disease.
- 3.2 Lanreotide acetate prolonged release depot suspension (Somatuline LA® 30 mg) was recommended as a Section 100 listing for the treatment of active acromegaly at the September 2001 PBAC meeting. Lanreotide Acetate (Somatuline Autogel) pre-filled syringe, 60 mg, 90 mg and 120 mg, was recommended for listing by the PBAC as a Section 100 HSD, for the treatment of acromegaly and for the treatment of the symptoms of carcinoid syndrome at its July 2005 meeting.

- 3.3 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 and hepatitis B medicines without the need to be affiliated with a hospital. In comparison to S100 HSD public and private hospital listings, community access arrangements remove the requirements for prescribers to demonstrate a link to a hospital setting. It also removes the requirements for private hospital prescribers to obtain phone authority, replacing the current authority requirements with streamlined authority; and for patients receiving care at/or from a hospital.



4 Clinical Place for the proposed therapy

- 4.1 The submission stated that patients living in rural areas, currently must travel into regional centres or major cities to be prescribed and dispensed Lanreotide Acetate. Therefore, the submission argued that a section 100 HSD Community Access Authority Required (Streamlined) listing for the drug would allow authorised community based practitioners to prescribe the drug without needing to be affiliated with a hospital and removing the burden of travel for patients living in rural areas.
- 4.2 The submission requested a Section 100 HSD (Community Access) listing for lanreotide acetate pre-filled syringe (Somatuline® Autogel®) as this formulation, in contrast to lanreotide acetate prolonged release depot suspension (Somatuline LA® 30 mg), does not require reconstitution and it is ready to be self- injected by the patient or administered by a care-giver following training.
- 4.3 The submission stated that training to use the injector and self-inject for patients or care-givers is provided by the Ipsen patient support program assistBEYOND.

5 Consideration of Evidence

Sponsor hearing

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

Consumer comments

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

Estimated PBS and financial implications

- 5.2 The submission presented the estimated net financial impact of the listing to the PBS/RPBS across the forward projections. The submission estimated a net savings to the PBS/RPBS, estimated to increase from less than \$10 million per year in 2017 to a saving of less than \$10 million per year by 2022. The secretariat noted that this estimated cost saving is not directly attributable to the requested change in this minor submission.

6 PBAC Outcome

- 6.1 The PBAC recommended to extend the current listing for lanreotide acetate 60 mg/0.5 mL, 90 mg/0.5 mL and 120 mg/0.5 mL pre-filled syringes, Somatuline Autogel pre-filled syringe from Section 100 Highly Specialised Drugs program (HSD) to a Section 100 HSD Community Access, Authority Required (STREAMLINED) for patients with acromegaly and functional carcinoid tumour under the conditions noted below.
- 6.2 The PBAC recommended that the continuing phase of treatment should be available under Section 100 - Highly Specialised Drugs Program (Community Access), whilst the initial phase of treatment should remain unchanged under Section 100 – Highly Specialised Drugs 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 highly specialised drug (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 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.

8 Sponsor's Comment

The sponsor had no comment.