

6.12 LANREOTIDE

Injection 120 mg (as acetate) in single dose pre-filled syringe

Somatuline® Autogel®, Ipsen Pty Ltd

1 Purpose of Application

- 1.1 The minor submission sought to extend the current listing of lanreotide injection 120 mg (as acetate) for the treatment of non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET) to include a Section 100 (Highly Specialised Drugs Program) (S100 HSD) – Community Access listing for continuing patients who have previously received treatment through the current S100 HSD – Public/Private Hospital listing.

2 Requested listing

- 2.1 The submission requested the following new listing.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer
LANREOTIDE 120 mg/0.5 mL injection, 0.5 mL syringe	2	5	Somatuline® Autogel®, Ipsen Pty Ltd

Category / Program	Section 100 (Highly Specialised Drugs) – Community Access
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners
PBS Indication:	Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)
Restriction Level / Method:	<input checked="" type="checkbox"/> Streamlined
Clinical criteria:	Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND The condition must be unresectable locally advanced or metastatic disease, AND The condition must be World Health Organisation (WHO) grade 1 or 2 AND The treatment must be as monotherapy
Population criteria:	Patient must be aged 18 years or older.

Prescriber Instructions	<p>WHO grade 1 of GEP-NETs is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.</p> <p>WHO grade 2 of GEP-NETs is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.</p> <p>Lanreotide is not PBS-subsidised for use in combination with everolimus or sunitinib for this condition.</p>
Administrative Advice	<p>No increase in the maximum quantity or number of units may be authorised.</p> <p>No increase in the maximum number of repeats may be authorised.</p> <p>Special Pricing Arrangements apply.</p>

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

3 Background

- 3.1 The PBAC recommended lanreotide for the treatment of non-functional GEP-NET subsequent to its consideration of a minor resubmission at its November 2017 meeting. Lanreotide was listed on the PBS through S100 HSD – Public/Private Hospital for the treatment of patients with non-functional GEP-NET on 1 December 2018.
- 3.2 In November 2017, the PBAC recommended to extend the S100 HSD listings for lanreotide 120 mg, 90 mg and 60 mg pre-filled syringes to include a S100 HSD – Community Access listing for continuing treatment of patients with acromegaly and functional carcinoid tumour. This submission made a similar request for a S100 HSD – Community Access listing of lanreotide 120 mg pre-filled syringe for adult patients receiving continuing treatment for non-functional GEP-NET.

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

4 Clinical place for the proposed therapy

- 4.1 The submission requested a S100 HSD – Community Access listing for lanreotide for non-functional GEP-NET with the intention of improving equity of access and the quality use of medications for patients located in rural areas. Patients in rural areas are currently required to travel into regional centres or major cities to see a medical oncologist at a public or private hospital and have their prescriptions dispensed by the hospital pharmacy. The submission presented a literature review with the intention of supporting the argument that patients in rural settings are more likely to have poorer health outcomes associated with the lack of access to appropriate treatment.
- 4.2 Compared with S100 HSD – Public/Private Hospital listings, the S100 HSD – Community Access arrangements remove the requirement for patients and prescribers to be affiliated with a hospital setting.
- 4.3 The submission stated that lanreotide 120 mg prefilled syringe is suitable for self or partner-administration as an outpatient.

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 To estimate the financial implications of the requested change, the minor submission used the epidemiological financial implications model that was evaluated as part of the non-functional GEP-NET submission.

5.4 The minor submission claimed that there would be no net increase in utilisation of lanreotide because of the additional Community Access listing and that additional costs to the Australian government will result from the additional mark-ups applied to Community Access listings, compared with Public Hospital listings. As the remuneration rates for HSDs dispensed through community pharmacies are aligned to those paid to private hospitals, the submission noted that there would be no financial implications associated with patients switching from the Private Hospital listing to Community Access.

5.5 The submission estimated that extending the listing for lanreotide for non-functional GET-NET to include a Community Access listing would result in an additional cost to the PBS/RPBS of around \$██████ in Year 1 to \$██████ in Year 6 of listing (see Table 1). Lanreotide has a special pricing arrangement for non-functional GEP-NET with a published and an effective price; the submission noted the financial implications are the same at both the published and effective prices.

Table 1: Utilisation and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
PBS/RPBS Utilisation						
S100 HSD - Community Access patients ^A	█	█	█	█	█	█
S100 HSD - Community Access packs ^B	█	█	█	█	█	█
Financial implications						
Net cost to the PBS/RPBS ^C	\$ █	\$ █	\$ █	\$ █	\$ █	\$ █

^A Assuming 25% of patients in Inner Regional Australia and 100% of patients in Outer Regional, Remote and Very Remote Australia will switch to S100 HSD – Community Access for continuing treatment (14.8% of total patients), based on population data estimates for regional localities published by the Australian Bureau of Statistics.

^B Assuming 13 packs per year and a 90% compliance rate (consistent with the assumptions in the July 2017 submission and the November 2017 pre-PBAC response for lanreotide for GET-NET).

^C Assuming an additional cost to the PBS/RPBS of \$47.29 for each S100 HSD – Public Hospital script replaced by a S100 HSD – Community Access script (assumed to be 63.4% of Community Access scripts).

The redacted table shows that at Year 6, the estimated number of patients will be less than 10,000 for s100 HSD Community Access patients and the cost to the PBS will be less than \$10 million.

- 5.6 The submission included sensitivity analyses to investigate the impact of changes in the assumed proportion of eligible patients utilising the Community Access arrangements. The submission estimated that if all patients receiving PBS subsidised lanreotide for GEP-NETs were to utilise the Community Access listing for continuing treatment, the additional cost to the PBS would be approximately less than \$10 million in Year 1 of listing to less than \$10 million in Year 6.
- 5.7 The submission stated that a Risk Sharing Arrangement is in place for lanreotide for non-functional GEP-NETs, which includes an annual cap of \$█ million in Government expenditure, with a 100% rebate for each dollar above that amount.

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

6 PBAC Outcome

- 6.1 The PBAC recommended extending the current listing of lanreotide acetate 120 mg/0.5 mL pre-filled syringe, Somatuline Autogel from Section 100 Highly Specialised Drugs program (HSD) to Section 100 HSD Community Access, Authority Required (STREAMLINED) for patients requiring continuing treatment of non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET).
- 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 a Community Access listing would improve access for patients receiving continuing treatment with lanreotide in rural areas, by removing the requirement for patients and prescribers to be affiliated with a hospital setting.

- 6.4 The PBAC noted that the minor submission claimed that there would be no net increase in utilisation of lanreotide for continuing treatment for non-functional GEP-NET because of the additional Community Access listing and that additional costs to the Australian government will result from the additional mark-ups applied to Community Access listings, compared with Public Hospital listings.
- 6.5 The PBAC advised that there should be no increase to the current subsidisation caps under the RSA for lanreotide for non-functional GEP-NETs, and noted that expenditure under the S100 HSD – Community Access listing would be captured under the existing Risk Sharing Arrangement.

Outcome:

Recommended

7 Recommended listing

- 7.1 Add new item:

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Administrative Advice	No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised. Special Pricing Arrangements apply.

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

The sponsor had no comment.