5.16 LANREOTIDE, Injection 60 mg (as acetate) in single dose pre-filled syringe Injection 90 mg (as acetate) in single dose pre-filled syringe Injection 120 mg (as acetate) in single dose pre-filled syringe LACREO®, Sun Pharma ANZ Pty Ltd

1 Purpose of Submission

1.1 The Category 4 submission requested to list three lanreotide pre-filled syringes (PFS) (LACREO®) under the same circumstances as the other PBS-listed brands of lanreotide. The syringes are a similar device to the currently PBS listed Somatuline Autogel and deliver the same doses of lanreotide. The strengths are:

- injection 60 mg (as acetate) in single dose PFS (60 PFS)
- injection 90 mg (as acetate) in single dose PFS (90 PFS)
- injection 120 mg (as acetate) in single dose PFS (120 PFS)

1.2 Listing was requested on the basis of a cost-minimisation basis versus Somatuline Autogel.

2 Background

2.1 Lanreotide is currently listed on the PBS as an Authority Required section 100 Highly Specialised Drug (s100 HSD) listing for acromegaly, functional carcinoid tumour and non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET).

Registration status

2.2 Lanreotide LACREO 60 PFS was TGA registered on 24 October 2025. Lanreotide LACREO 90 PFS and 120 PFS were TGA registered on 22 October 2025. All 3 strengths of LACREO were approved for the same indications as are approved for Somatuline Autogel. They are:

- the treatment of acromegaly when the circulating levels of growth hormone and IGF-1 remain abnormal after surgery and/or radiotherapy or in patients who are dopamine agonist treatment refractory;
- the treatment of symptoms of carcinoid syndrome associated with carcinoid (neuroendocrine) tumours;

- the treatment of gastroenteropancreatic neuroendocrine tumours (GEP-NETs) in adult patients with unresectable locally advanced or metastatic disease.

Previous PBAC consideration

2.3 Lanreotide was previously considered multiple times by the PBAC between 2001 - 2024. A paraphrased summary has been provided in Table 1. Further detail of previous considerations can be found in published Public Summary Documents (PSD).

Table 1: Previous PBAC considerations

Meeting date	Brand	Lanreotide Form	Listing Type & Indication	Outcome
September 2001	Somatuline LA	IM injection 30 mg	s100HSD – acromegaly	Recommended
September 2003	Somatuline Autogel	PFS 60 mg, 90 mg, 120 mg	s100HSD – acromegaly	Recommended
July 2005	Somatuline Autogel	PFS 60 mg, 90 mg and 120 mg	s100HSD – carcinoid syndrome	Recommended
March 2007	Somatuline Autogel	PFS 60 mg, 90 mg and 120 mg	Amendment to existing carcinoid syndrome	Recommended
November 2015	Somatuline Autogel	PFS 120 mg	s85 - GEP-NETs	Not recommended
November 2016	Somatuline Autogel	PFS 120 mg	s100HSD - GEP-NETs	Not recommended
July 2017	Somatuline Autogel	PFS 120 mg	s100HSD – GEP-NETs	Not recommended
November 2017	Somatuline Autogel	PFS 120mg	s100HSD – GEP-NETs	Deferred
November 2017	Somatuline Autogel	PFS 60 mg, 90 mg and 120 mg	s100HSD CA - acromegaly & carcinoid syndrome	Recommended
March 2019	Somatuline Autogel	PFS 120mg	s100HSD CA – GEP-NETs	Recommended
November 2022	Mytolac®	PFS 60 mg, 90 mg and 120 mg	s100HSD – acromegaly, carcinoid syndrome & GEP-NETs	Recommended

Source: prepared by the PBAC Secretariat

Abbreviations: IM = intramuscular; s100HSD = section 100 Highly Specialised Drug; PFS = pre-filled syringe; s85 = section 85 General Schedule; GEP-NET = Gastroenteropancreatic neuroendocrine tumours; CA = Community Access.

3 Requested listing

3.1 The submission requested to add a generic brand under identical circumstances as the existing listings, for brevity the full restrictions have not been reproduced below.

Add medicinal product pack: acromegaly, functional carcinoid tumour

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
LANREOTIDE					
lanreotide 60 mg/0.2 mL injection 0.2 mL syringe	*New (HB)* *New (HS)* *New (CA)*	2	2	5	LACREO
lanreotide 90 mg/0.3 mL injection 0.3 mL syringe	*New (HB)* *New (HS)* *NEW (CA)*	2	2	5	LACREO
lanreotide 120 mg/0.5 mL injection 0.5 mL syringe	11289E (CA) 5779E (HB) 6425E (HS)	2	2	5	Somatuline Autogel Mytolac LACREO
	Indication: Acromegaly				
	Indication: Functional carcinoid tumour				
	Administrative Advice: Somatuline Autogel, Mytolac and *LACREO* products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.				

Add medicinal product pack: non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
LANREOTIDE					
lanreotide 60 mg/0.2 mL injection 0.2 mL syringe	*New (HB)* *New (HS)* *New (CA)*	2	2	5	LACREO
lanreotide 90 mg/0.3 mL injection 0.3 mL syringe	*New (HB)* *New (HS)* *NEW (CA)*	2	2	5	LACREO
lanreotide 120 mg/0.5 mL injection 0.5 mL syringe	11513Y (HB) 11527Q (HS) 11736Q (CA)	2	2	5	Somatuline Autogel Mytolac LACREO
	Indication: Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)				
	Administrative Advice: Somatuline Autogel, Mytolac and *LACREO* products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.				

3.2 Due to differences in the syringe volume between LACREO and the currently listed brands for the 60 mg and 90 mg injections, new item codes will be created for these strengths.

3.3 Flow on changes to the existing item codes for lanreotide 60 mg/0.5mL syringe and 90 mg/0.5mL will be required to add LACREO to the overarching administrative note as follows:

	Administrative Advice: Somatuline Autogel, Mytolac and *LACREO* products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

4 Comparator

4.1 The submission nominated lanreotide (Somatuline Autogel) as the main comparator.

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item.

Consumer input

5.2 The PBAC noted and welcomed input from Rare Cancers Australia which described the physical, psychological and daily burden for patients living with acromegaly, functional carcinoid tumour and GEP-NET. The input described a range of benefits of treatment with lanreotide, including reduced treatment and financial burden and improvement in overall quality of life.

Clinical claim

5.3 The submission's request was based on bioequivalence to the originator brand, Somatuline Autogel. The Therapeutic Goods Administration (TGA) provided an approval letter establishing that LACREO is bioequivalent on 19 September 2025.

Economic analysis

5.4 The submission presented a cost-minimisation approach of LACREO compared with Somatuline Autogel. The equi-effective doses were estimated as:

LACREO 60 mg/0.2 mL injection 0.2 mL syringe	=	Somatuline Autogel 60 mg/0.5 mL injection 0.5 mL syringe
LACREO 90 mg/0.3 mL injection 0.3 mL syringe	=	Somatuline Autogel 90 mg/0.5 mL injection 0.5 mL syringe
LACREO 120 mg/0.5 mL injection 0.5 mL syringe	=	Somatuline Autogel 120 mg/0.5 mL injection 0.5 mL syringe

5.5 The requested price was based on the AEMP of Somatuline Autogel, in February 2026.

Estimated PBS usage and financial implications

5.6 Table 2 presents the estimated extent of use, cost of LACREO to the PBS/RPBS and the net financial implications to the PBS/RPBS and MBS. The financial impact to Services Australia will be determined by that agency as part of the post PBAC process.

5.7 The submission estimated that 30,000 to < 40,000 LACREO scripts would be supplied over the first six years of listing (500 to < 5,000 in Year 1 to 5,000 to < 10,000 in Year 6).

- The submission stated that the estimated net financial impact to the PBS/RPBS for the listing of LACREO is $0 over six years.

Table 2: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of scripts dispensed	[redacted][1]	[redacted][1]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]
Estimated financial implications of LACREO						
Cost to PBS/RPBS less co-payment	$[redacted][3]	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]
Estimated financial implications of Somatuline Autogel						
Cost to PBS/RPBS less co-payment	-$[redacted][3]	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]
Net financial implications						
Net cost to PBS/RPBS	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**

Abbreviations: MBS = Medical Benefits Scheme; PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.
Source: Table 3.2, page 8 of the submission.
The redacted values correspond to the following ranges:
[1] *500 to < 5,000*
[2] *5,000 to < 10,000*
[3] *$0 to < $10 million*
[4] *$10 million to < $20 million*

6 PBAC Outcome

6.1 The PBAC recommended the listing of lanreotide (LACREO), for the treatment of acromegaly, functional carcinoid tumour and non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET) on the basis that it should be available only under special arrangements under the Section 100 Highly Specialised Drugs (HSD) Program Community Access under the same circumstances as PBS-listed originator brand Somatuline Autogel®.

6.2 The PBAC advised the equi-effective doses to be 1 mg LACREO equals 1 mg Somatuline Autogel.

6.3 The PBAC advised that, under Section 101(4AACD) of the *National Health Act 1953*, the following drug/strength/forms of LACREO and Somatuline Autogel should be

considered equivalent for the purpose of substitution at the pharmacy level (i.e., 'a' flagged in the Schedule of Pharmaceutical Benefits):

- LACREO 60 mg/0.2 mL injection 0.2 mL syringe and Somatuline Autogel 60 mg/0.5 mL injection 0.5 mL syringe
- LACREO 90 mg/0.3 mL injection 0.3 mL syringe and Somatuline Autogel 90 mg/0.5 mL injection 0.5 mL syringe
- LACREO 120 mg/0.5 mL injection 0.5 mL syringe and Somatuline Autogel 120 mg/0.5 mL injection 0.5 mL syringe

6.4 The PBAC considered that the nominated comparator of lanreotide (Somatuline Autogel) was appropriate, and noted the opinion of the TGA that lanreotide (LACREO) was bioequivalent to lanreotide (Somatuline Autogel).

6.5 The PBAC considered the economic model and utilisation estimates to be reasonable. The PBAC noted that the recommended listing was made as a cost minimisation and would be cost neutral to the PBS.

6.6 The PBAC considered lanreotide (LACREO) to be suitable for prescribing by medical practitioners only.

6.7 As a flow-on to the recommendation to list lanreotide (LACREO) under the s100 HSD Program Community Access, the PBAC noted that the s100 HSD Program public and private hospital listings for lanreotide (all brands/forms) should be removed, as the HSD Program Community Access listings provide for access in community, public and private hospital settings.

6.8 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because lanreotide (LACREO) is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over lanreotide (Somatuline Autogel), or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.

6.9 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:
Recommended

7 Recommended listing

Add medicinal product packs (additions in *italic*, deletions in ~~strikethrough~~):

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
LANREOTIDE					
lanreotide 60 mg/0.2 mL injection, 0.2 mL syringe	*NEW1*	2	2	5	Lacreo
lanreotide 90 mg/0.3 mL injection 0.3 mL syringe	*NEW2*	2	2	5	Lacreo
lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe	11289E	2	2	5	Somatuline Autogel Mytolac *Lacreo*

Concept ID	**Category / Program:** ☒ Section 100 – Highly Specialised Drugs Program – Community Access (CA)
	Prescriber type: ☒Medical Practitioners
	Benefit type: ☒Authority Required (Streamlined) [new/existing code]
	Authority type: ☒ Non-complex Authority Required (non-CAR)
	Administrative Advice: Somatuline Autogel, ~~and~~ Mytolac and *LACREO* products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.
	Indication: Acromegaly
	Treatment Phase: Initial treatment
	Treatment Criteria:
	Must be treated by a specialist practicing in a hospital who is either: (i) an endocrinologist, (ii) an oncologist; or
	Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types within a hospital setting
	AND
	Clinical criteria:
	The condition must be active
	AND
	Clinical criteria:
	Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre
	AND
	Clinical criteria:
	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
	Clinical criteria:
	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
	Clinical criteria:

	The treatment must cease if IGF1 is not lower after 3 months of treatment
	AND
	Clinical criteria:
	The treatment must not be given concomitantly with PBS-subsidised pegvisomant
	Prescribing Instructions: In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission
	Indication: Acromegaly
	Treatment Phase: Continuing treatment
	Clinical criteria:
	Patient must have previously received PBS-subsidised treatment with this drug for this condition
	AND
	Clinical criteria:
	The condition must be active
	AND
	Clinical criteria:
	Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre
	AND
	Clinical criteria:
	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
	Clinical criteria:
	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
	Clinical criteria:
	The treatment must cease if IGF1 is not lower after 3 months of treatment
	AND
	Clinical criteria:
	The treatment must not be given concomitantly with PBS-subsidised pegvisomant
	Prescribing Instructions: In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission
	Indication: Functional carcinoid tumour
	Treatment Phase: Initial treatment
	Treatment Criteria:

	Must be treated by a specialist practicing in a hospital who is either: (i) an endocrinologist, (ii) an oncologist; or
	Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types within a hospital setting
	AND
	Clinical criteria:
	The condition must be causing intractable symptoms
	AND
	Clinical criteria:
	Patient 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
	Clinical criteria:
	Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate
	AND
	Clinical criteria:
	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
	Prescribing 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.
	Indication: Functional carcinoid tumour
	Treatment Phase: Continuing treatment
	Clinical criteria:
	Patient must have previously received PBS-subsidised treatment with this drug for this condition
	AND
	Clinical criteria:
	The condition must be causing intractable symptoms
	AND
	Clinical criteria:
	Patient 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
	Clinical criteria:
	Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate
	AND
	Clinical criteria:
	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
	Prescribing 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.

MEDICINAL PRODUCT medicinal product pack		PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
LANREOTIDE						
lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe		11736Q	2	2	5	Somatuline Autogel Mytolac *Lacreo*
Concept ID	**Category / Program:** ☒ Section 100 – Highly Specialised Drugs Program – Community Access (CA)					
	Prescriber type: ☒Medical Practitioners					
	Benefit type: ☒Authority Required (Streamlined) [new/existing code]					
	Authority type: ☒ Non-complex Authority Required (non-CAR)					
	Administrative Advice: Somatuline Autogel, ~~and~~ Mytolac and *LACREO* products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.					
	Administrative Advice: No increase in the maximum quantity or number of units may be authorised					
	Administrative Advice: No increase in the maximum number of repeats may be authorised					
	Indication: Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)					
	Treatment Phase: Initial treatment					
	Treatment Criteria:					
	Must be treated by a specialist practicing in a hospital who is either: (i) an endocrinologist, (ii) an oncologist; or					
	Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types within a hospital setting					
	AND					
	Clinical criteria:					
	The condition must be unresectable locally advanced disease or metastatic disease					
	AND					
	Clinical criteria:					
	The condition must be World Health Organisation (WHO) grade 1 or 2					
	AND					
	Clinical criteria:					
	The treatment must be either: (i) as monotherapy, (ii) in combination with cabozantinib					
	AND					
	Population criteria:					
	Patient must be at least 18 years of age					
	Prescribing Instructions: WHO grade 1 of GEP-NET is defined at a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.					
	Prescribing Instructions: WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20					
	Restriction Summary 17658 / Treatment of Concept: 17696					
	Indication: Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)					
	Treatment Phase: Continuing treatment					

	Clinical criteria:
	Patient must have previously received PBS-subsidised treatment with this drug for this condition
	AND
	Clinical criteria:
	The condition must be unresectable locally advanced disease or metastatic disease
	AND
	Clinical criteria:
	The condition must be World Health Organisation (WHO) grade 1 or 2
	AND
	Clinical criteria:
	The treatment must be either: (i) as monotherapy, (ii) in combination with cabozantinib
	AND
	Population criteria:
	Patient must be at least 18 years of age
	Prescribing Instructions: WHO grade 1 of GEP-NET is defined at a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.
	Prescribing Instructions: WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20

Flow-ons:
As a result of the PBAC's recommended listing for lanreotide (LACREO) as a s100 HSD Program Community Access listing, the s100 HSD Program Public and Private hospital listings for lanreotide (all brands/forms) will be removed. The PBS item codes affected are as follows:

- *5779E*
- *6425E*
- *11513Y*
- *11527Q*
- *5777C*
- *6423C*
- *5778D*
- *6424D*

These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.

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.