

**5.13 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,
Mytolac[®],
Amdipharm Mercury (Australia) Pty Limited**

1 Purpose of Submission

- 1.1 The Category 3 submission sought Section 100 (S100) Highly Specialised Drug Program (HSD) Authority Required (STREAMLINED) listings of a new brand of lanreotide (Mytolac[®]) 60 mg, 90 mg and 120 mg (as acetate) in pre-filled, single use syringes under the same circumstances as the PBS-listed reference brand Somatuline Autogel[®].

2 Background

Registration status

- 2.1 Mytolac was registered on the Australian Register for Therapeutic Goods (ARTG) on 10 August 2022 for:
- 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 tumours
 - the treatment of gastroenteropancreatic neuroendocrine tumours (GEP-NETs) in adult patients with unresectable locally advanced or metastatic disease.
- 2.2 Mytolac was determined by the Therapeutic Goods Administration (TGA) to be bioequivalent to Somatuline Autogel solution for injection.

Previous PBAC consideration

- 2.3 Lanreotide (Somatuline Autogel) has been considered by the PBAC at the following meetings:
- July 2005 – recommended for listing under S100 HSD for carcinoid tumour.

- November 2015, November 2016, July 2017 – rejected for non-functional GEP-NETs.
- November 2017 – recommended listing under S100 HSD (Community Access) for acromegaly and functional carcinoid tumour.
- November 2017 – recommended listing under S100 HSD for non-functional GEP-NETs.
- March 2019 – recommended listing under S100 HSD (Community Access) for non-functional GEP-NETs

2.4 The Mytolac brand of lanreotide has not previously been considered by the PBAC.

Current status

- 2.5 Somatuline Autogel, the reference brand, is listed on the PBS for the same strengths, forms and manner of administration. It is currently listed for acromegaly, functional carcinoid tumour and non-functional GEP-NETs.
- 2.6 The PBAC noted that, if listed, Mytolac will be the first PBS-listed bioequivalent brand of lanreotide. The submission noted that this would trigger a first new brand statutory price reduction under Division 3A of the Act.

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

3 Requested listing

3.1 The submission requested the following restrictions and proposed no changes to the existing listing except to add Mytolac as a new brand.

| MEDICINAL PRODUCT Medicinal Product Pack | PBS item code | Max. qty packs | Max. qty units | No. of Rpts | Available brands |
|--|--|-------------------|-------------------|----------------|---|
| LANREOTIDE | | | | | |
| lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe | 11315M 6423C 5777C | 2 | 2 | 5 | ^a Mytolac [NEW] ^a Somatuline Autogel |
| lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe | 11316N 6424D 5778D | 2 | 2 | 5 | ^a Mytolac [NEW] ^a Somatuline Autogel |
| lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe | 11289E 6425E 5779E 11736Q 11527Q 11513Y | 2 | 2 | 5 | ^a Mytolac [NEW] ^a Somatuline Autogel |

3.2 For the 60 mg, 90 mg and 120 mg strengths, the submission requested restrictions identical to the current lanreotide listings for the treatment of acromegaly and functional carcinoid tumour, and for the 120 mg strength, restrictions identical to the current listings for treatment of non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET).

- 3.3 The submission included a completed Australian Medicines Terminology (AMT) form that showed the Medicinal Product Pack (MPP) for Mytolac to be identical to that of Somatuline Autogel for each respective strength. Additionally, the requested listing instrument form of Mytolac was identical to that of Somatuline Autogel. The PBAC considered that Mytolac was sufficiently similar to Somatuline Autogel such that it would fit under the same listing instrument form (and therefore the same pharmaceutical item) and be considered a new brand of lanreotide.
- 3.4 The submission requested that Mytolac be ‘a’-flagged to Somatuline Autogel, despite being packaged differently. Further discussion is included in the ‘Quality Use of Medicines’ section below.

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

4 Comparator

- 4.1 The submission nominated Somatuline Autogel as the main comparator. The PBAC considered that this was appropriate.

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.

Consumer comments

- 5.2 The PBAC noted and welcomed input from NeuroEndocrine Cancer Australia (NECA) via the Consumer Comments facility on the PBS website. The NECA comments described how the benefits of treatment with lanreotide were not limited to the reduction of symptoms from NETs but highlighted recent clinical trial results which showed that lanreotide significantly improved progression-free survival compared to placebo in patients with non-functioning intestinal or pancreatic neuroendocrine tumours (NETs). NECA also raised concerns with administration site pain, the lack of an at-home injection program, that patients were not comfortable self-injecting, and concerns about health care provider training in administering the drug. NECA presented the views of a NET healthcare professional that the two-piece design for Mytolac may not be user friendly due to the need to screw the needle on.
- 5.3 The PBAC noted the quality use of medicines (QUM) concerns presented by NECA and considered that the submission adequately addressed these as noted in paragraph 5.15.

Clinical claim

- 5.4 The submission claimed that Mytolac is a generic version of Somatuline Autogel and that the active component is chemically identical. In the Mytolac approval letter, the

TGA stated that Mytolac “can be considered bioequivalent to Somatuline Autogel” and that there were no clinically meaningful differences between Mytolac and Somatuline Autogel.

- 5.5 The PBAC considered that the claim of non-inferior comparative effectiveness was reasonable.

Estimated PBS utilisation and financial implications

- 5.6 The requested price was based on the approved ex-manufacturer price (AEMP) of Somatuline Autogel and incorporating the anticipated First New Brand statutory price reduction (FNB SPR).
- 5.7 The submission used a market share approach to describe the estimated utilisation and financial impacts of listing Mytolac over the six-year calendar period between 2023 and 2028 in public and private hospitals, and community settings.
- 5.8 The submission did not anticipate the listing of Mytolac to impact the size of the lanreotide market with the assumption that the listing of the drug would only replace a proportion of the existing market and not lead to an increase in utilisation. The PBAC considered this to be appropriate.
- 5.9 The submission presented estimated utilisation and financial estimates for the acromegaly and functional carcinoid tumours indications dispensed at both public and private hospitals (Table 1) and dispensed at community pharmacies (Table 2).

Table 1: Estimated financial impact of listing lanreotide (Mytolac) for PBS items 5777C, 5778D, 5779E (\$100HSD public) and 6423C, 6424D, 6425E (\$100HSD private) for the acromegaly and functional carcinoid tumours

| PBS | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 |
|--------------------------|------|------|------|------|------|------|
| New listing (\$) | 1 | 1 | 1 | 1 | 1 | 1 |
| Changed listing (\$) | 2 | 2 | 2 | 2 | 2 | 2 |
| Net cost to PBS | 1 | 1 | 1 | 1 | 1 | 1 |
| RPBS | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 |
| New listing (\$) | 1 | 1 | 1 | 1 | 1 | 1 |
| Changed listing (\$) | 2 | 2 | 2 | 2 | 2 | 2 |
| Net cost to RPBS (\$) | 1 | 1 | 1 | 1 | 1 | 1 |
| Net cost PBS / RPBS (\$) | 1 | 1 | 1 | 1 | 1 | 1 |

Source: Submission main body p. 29.

These estimates show the net cost to the PBS without the FNB SPR having been applied.

The redacted values correspond to the following ranges:

¹ \$0 to < \$10 million

² net cost saving

Table 2: Estimated financial impact of listing lanreotide (Mytolac) for PBS items 11315M, 11316N, 11289E (S100HSD Community) for the acromegaly and functional carcinoid tumours

| PBS | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 |
|---------------------------------|----------|----------|----------|----------|----------|----------|
| New listing (\$) | 1 | 1 | 1 | 1 | 1 | 1 |
| Changed listing (\$) | 2 | 2 | 2 | 2 | 2 | 2 |
| Net cost to PBS (\$) | 1 | 1 | 1 | 1 | 1 | 1 |
| | | | | | | |
| RPBS | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 |
| New listing (\$) | 1 | 1 | 1 | 1 | 1 | 1 |
| Changed listing (\$) | 2 | 2 | 2 | 2 | 2 | 2 |
| Net cost to RPBS (\$) | 1 | 1 | 1 | 1 | 1 | 1 |
| | | | | | | |
| Net cost PBS / RPBS (\$) | 1 | 1 | 1 | 1 | 1 | 1 |

Source: Submission main body p. 29-30.

These estimates show the net cost to the PBS without the FNB SPR having been applied.

The redacted values correspond to the following ranges:

¹ \$0 to < \$10 million

² net cost saving

5.10 The estimated utilisation and financial implications for the use of lanreotide in non-functional GEP-NET was presented as two tables; prescriptions dispensed in public and private hospitals (Table 3) and prescriptions dispensed in community pharmacies (Table 4).

Table 3: Estimated financial impact of listing lanreotide (Mytolac) for PBS items 11513Y (S100HSD public) and 11527Q (S100HSD private) for non-functional GEP-NET

| PBS | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 |
|---------------------------------|----------|----------|----------|----------|----------|----------|
| New listing (\$) | 1 | 1 | 1 | 1 | 1 | 1 |
| Changed listing (\$) | 2 | 2 | 2 | 2 | 2 | 2 |
| Net cost to PBS (\$) | 1 | 1 | 1 | 1 | 1 | 1 |
| | | | | | | |
| RPBS | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 |
| New listing (\$) | 1 | 1 | 1 | 1 | 1 | 1 |
| Changed listing (\$) | 2 | 2 | 2 | 2 | 2 | 2 |
| Net cost to RPBS (\$) | 1 | 1 | 1 | 1 | 1 | 1 |
| | | | | | | |
| Net cost PBS / RPBS (\$) | 1 | 1 | 1 | 1 | 1 | 1 |

Source: Submission main body p. 30 and the financial estimates workbooks. Table is mis-labelled in the submission main body.

These estimates show the net cost to the PBS without the FNB SPR having been applied.

The redacted values correspond to the following ranges:

¹ \$0 to < \$10 million

² net cost saving

Table 4: Estimated financial impact of listing lanreotide (Mytolac) for PBS items 11736Q (S100HSD Community) for non-functional GEP-NET

| PBS | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 |
|--------------------------|------|------|------|------|------|------|
| New listing (\$) | 1 | 1 | 1 | 1 | 1 | 1 |
| Changed listing (\$) | 2 | 2 | 2 | 2 | 2 | 2 |
| Net cost to PBS (\$) | 1 | 1 | 1 | 1 | 1 | 1 |
| | | | | | | |
| RPBS | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 |
| New listing (\$) | 1 | 1 | 1 | 1 | 1 | 1 |
| Changed listing (\$) | 2 | 2 | 2 | 2 | 2 | 2 |
| Net cost to RPBS (\$) | 1 | 1 | 1 | 1 | 1 | 1 |
| | | | | | | |
| Net cost PBS / RPBS (\$) | 1 | 1 | 1 | 1 | 1 | 1 |

Source: Submission main body p. 30-31.

These estimates show the net cost to the PBS without the FNB SPR having been applied.

The redacted values correspond to the following ranges:

¹ \$0 to < \$10 million

² net cost saving

5.11 As a Category 3 submission, the utilisation and financial analysis was not independently evaluated.

Quality Use of Medicines

5.12 Mytolac is supplied in a two-part pre-filled syringe with a separately packed safety needle that is attached immediately prior to use. The two parts consist of the pre-filled syringe and an automatic single-use needle-safe device. Patients would need to connect these components together to successfully administer the drug.

5.13 Somatuline Autogel is supplied as a single part pre-filled syringe with the safety needle already attached that is ready to use and is fitted with an automatic safety system.

5.14 The submission requested that Mytolac and Somatuline Autogel be considered equivalent for the purposes of substitution ('a' flagged). In support of this request, the sponsor advised it would undertake the following steps, informed by its roll-out in European countries:

1. Provide training and support for clinicians in how to use and train patients to use the device including:
 - a) hospital clinical staff training and support, and
 - b) a community pharmacist training program and kit;
2. Provide online nursing support for patients to access assistance when administering the product at home;
3. Include a pack insert with clear and comprehensive instructions on how to administer Mytolac; and
4. Provide a Dear Healthcare Professional letter (as requested by the TGA during its evaluation).

The PBAC considered that this was appropriate

- 5.15 The submission noted that the sponsor has updated the colour of the packaging of the three different strengths to match the colours of the originator brand to prevent confusion for end users. The PBAC considered that this was appropriate.

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

6 PBAC Outcome

- 6.1 The PBAC recommended the Authority Required (STREAMLINED) listing of lanreotide (Mytolac®) 60 mg, 90 mg and 120 mg (as acetate) in pre-filled, single use syringe as part of the Section 100 Highly Specialised Drug Program under the same circumstances as the PBS-listed reference brand Somatuline Autogel®. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost effectiveness of Mytolac would be acceptable if it were cost minimised to Somatuline Autogel for the same indications.
- 6.2 The PBAC advised the equi-effective doses to be to be 1 mg of Mytolac = 1 mg of Somatuline Autogel.
- 6.3 The PBAC considered that the nominated comparator, Somatuline Autogel, was appropriate. The PBAC noted that Mytolac is considered bioequivalent to Somatuline Autogel, and if listed, would be the first PBS-listed bioequivalent brand to Somatuline Autogel.
- 6.4 The PBAC noted the concerns raised by the consumer comments regarding healthcare professional training and QUM. The PBAC noted that the submission highlighted the training and education programs the sponsor intends to use to ensure the QUM for lanreotide. The PBAC noted that Mytolac is presented as a two-piece pre-filled syringe where Somatuline Autogel is a one-piece pre-filled syringe and considered that healthcare professional training and online nursing support for patients would need to be provided. The PBAC considered that the steps the submission had highlighted to ensure the QUM of lanreotide administration were appropriate.
- 6.5 The PBAC advised, under Section 101 (4AACD) of the Act, that lanreotide (as acetate) in pre-filled, single use syringe (Mytolac) and lanreotide (as acetate) in pre-filled, single use syringe (Somatuline Autogel) should be considered equivalent for the purposes of substitution (i.e., 'a' flagged in the Schedule) with an administrative note stating that pharmacists should ensure that patients are educated regarding the product differences upon dispensing.). The PBAC considered that the Mytolac was sufficiently similar to Somatuline Autogel such that it would fit under the same listing instrument form (and therefore the same pharmaceutical item) on the Schedule and be considered a new brand of Somatuline Autogel.
- 6.6 The PBAC considered that Mytolac would only substitute for Somatuline Autogel and therefore did not expect the lanreotide market to grow.
- 6.7 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because Mytolac is not expected to provide a substantial and clinically

relevant improvement in efficacy, or reduction of toxicity, over 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.

- 6.8 The PBAC noted the flow-on restriction changes to the Somatuline Autogel listings to accommodate the administrative note stating that pharmacists should ensure that patients are educated regarding the correct administration of the injection upon dispensing.
- 6.9 The PBAC noted that this submission is not eligible for an Independent Review as the PBAC has made a positive recommendation.

Outcome:

Recommended

7 Recommended listing

- 7.1 The restrictions for Mytolac in the 60 mg, 90 mg, and 120 mg strengths, for treatment of acromegaly and functional carcinoid tumour, are to be identical to the current Somatuline Autogel listings. An administrative advice note will be added to the listings for both Mytolac and Somatuline Autogel to confirm that “Somatuline Autogel and Mytolac products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.” The recommended listing is as follows:

| MEDICINAL PRODUCT medicinal product pack | PBS item code | Max. qty packs | Max. qty units | No. of Rpts | Available brands |
|--|--|-------------------|-------------------|----------------|---|
| LANREOTIDE | | | | | |
| lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe | 11315M | 2 | 2 | 5 | ^a Mytolac ^a Somatuline Autogel |
| lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe | 11316N | 2 | 2 | 5 | ^a Mytolac ^a Somatuline Autogel |
| lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe | 11289E | 2 | 2 | 5 | ^a Mytolac ^a Somatuline Autogel |
| Restriction Summary [7575] / Treatment of Concept: [7532] | | | | | |
| Concept ID (for internal Dept. use) | Category / Program: S100 HSD Community Access | | | | |
| | Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners | | | | |
| | Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined) [7532] | | | | |
| | Administrative Advice: Somatuline Autogel and Mytolac products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing. | | | | |
| | Indication: Acromegaly | | | | |
| | Clinical criteria: | | | | |
| | Patient must have previously received PBS-subsidised treatment with this drug for this condition | | | | |
| | AND | | | | |

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| | 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. |
| Restriction Summary [7508] / Treatment of Concept: [7509] | |
| | Indication: Functional carcinoid tumour |
| | 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 |

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| | 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 | No. of Rpts | Available brands |
|--|---|----------------|----------------|-------------|---|
| LANREOTIDE | | | | | |
| lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe | 5777C (HSD Public) 6423C (HSD Private) | 2 | 2 | 5 | ^a Mytolac ^a Somatuline Autogel |
| lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe | 5778D (HSD Public) 6424D (HSD Private) | 2 | 2 | 5 | ^a Mytolac ^a Somatuline Autogel |
| lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe | 5779E (HSD Public) 6425E (HSD Private) | 2 | 2 | 5 | ^a Mytolac ^a Somatuline Autogel |

Restriction Summary [7025],[9261] / Treatment of Concept: [7025],[9261]

| | |
|---|--|
| Concept ID (for internal Dept. use) | Category / Program: S100 HSD Public/Private |
| | Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners |
| | Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined) [7025] [9261] |
| | Administrative Advice: Somatuline Autogel and Mytolac products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing. |
| | Indication: Acromegaly |
| | 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. |
| Restriction Summary [4575],[9260] / Treatment of Concept: [4575],[9260] | |
| | Indication: Functional carcinoid tumour |
| | 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. |

7.2 The restriction for Mytolac in the 120 mg strength for the treatment of non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET) is to be identical to the current Somatuline Autogel listings. An administrative advice note will be added to the listings for both Mytolac and Somatuline Autogel to confirm that “Somatuline Autogel and Mytolac products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.” The recommended listing is as follows:

| MEDICINAL PRODUCT medicinal product pack | PBS item code | Max. qty packs | Max. qty units | No.of Rpts | Available brands |
|--|--|-------------------|-------------------|---------------|---|
| LANREOTIDE | | | | | |
| lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe | 11736Q | 2 | 2 | 5 | ^a Mytolac ^a Somatuline Autogel |
| Restriction Summary [10075] / Treatment of Concept: [10075] | | | | | |
| Concept ID (for internal Dept. use) | Category / Program: S100 HSD Community Access | | | | |
| | Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners | | | | |
| | Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined) [10075] | | | | |
| | Administrative Advice: Somatuline Autogel and Mytolac 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. | | | | |

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| | Indication: Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET) |
| | 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 the sole PBS-subsidised therapy for this condition |
| | AND |
| | Population criteria: Patient must be aged 18 years or older |
| | |
| | Prescribing Instructions: WHO grade 1 of GEP-NET is defined as 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. |

| MEDICINAL PRODUCT medicinal product pack | PBS item code | Max. qty packs | Max. qty units | No. of Rpts | Available brands |
|---|---|-------------------|-------------------|----------------|---|
| LANREOTIDE | | | | | |
| lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe | 11513Y (HSD Public) 11527Q (HSD Private) | 2 | 2 | 5 | ^a Mytolac ^a Somatuline Autogel |

Restriction Summary [10061],[10072] / Treatment of Concept: [10061],[10077]

| | |
|--|--|
| Concept ID (for internal Dept. use) | Category / Program: S100 HSD Public/Private |
| | Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners |
| | Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined) [10061],[10077] |
| | Administrative Advice: Somatuline Autogel and Mytolac 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) |
| | 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 the sole PBS-subsidised therapy for this condition |
| | AND |
| | Population criteria: |
| | Patient must be aged 18 years or older |
| | |
| | Prescribing Instructions: WHO grade 1 of GEP-NET is defined as 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. |

This restriction 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.