CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Somatostatin Analogs – Lanreotide Products Utilization Management Medical Policy
- Lanreotide subcutaneous injection – Cipla
- Somatuline® Depot (lanreotide subcutaneous injection – Ipsen, generic)

REVIEW DATE: 04/08/2026

OVERVIEW

The lanreotide products are somatostatin analogs indicated for the following uses:[1,2]

- **Acromegaly**, in patients who have had an inadequate response to surgery and/or radiotherapy, or for those whom surgery and/or radiotherapy, is not an option. The goal of treatment in acromegaly is to reduce growth hormone and insulin-like growth factor-1 levels to normal.
- **Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)**, in adult patients with unresectable, well or moderately differentiated, locally advanced or metastatic GEP-NETs to improve progression-free survival.
- **Carcinoid syndrome,** in adult patients to reduce the frequency of short-acting somatostatin analog rescue therapy.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for **neuroendocrine and adrenal tumors** (version 3.2025 – October 1, 2025) recommend lanreotide for the management of carcinoid syndrome; tumors of the gastrointestinal tract, lung, thymus (carcinoid tumors), and pancreas (including glucagonomas, gastrinomas, VIPomas, insulinomas); pheochromocytomas; and paragangliomas.[3] Patients who have local unresectable disease and/or distant metastases and clinically significant tumor burden or progression should be started on therapy with a somatostatin analog to potentially control tumor growth.

The 2025 international Acromegaly Consensus Statement reaffirms somatostatin analogs as the first-line medical therapy for most patients with persistent or non-surgically managed disease, with goals of insulin-like growth factor 1 (IGF-1) normalization, symptom control, and tumor growth prevention.[5] Injectable octreotide and lanreotide achieve biochemical control in approximately 40% of patients, with dose escalation or increased dosing frequency recommended before switching therapy. Mycapssa® (octreotide delayed-release capsules) is considered non-inferior to injectable somatostatin analogs in patients previously controlled on injectables and may be selected based on patient preference and adherence. Signifor® LAR (pasireotide intramuscular injection**)** provides greater efficacy in some inadequately controlled patients but carries a higher risk of hyperglycemia, and the consensus emphasizes individualized therapy selection and increasing use of combination therapy with Somavert® (pegvisomant subcutaneous injection) for partial responders.

The Endocrine Society Clinical Practice Guidelines (2014) recommend medical therapy primarily as adjuvant treatment following surgery, with somatostatin analogs used when surgery is not curative or the patient is a poor surgical candidate.[6] No preferred somatostatin analog is specified, and Mycapssa is not addressed in the 2014 guidelines. Subsequent updates from the Acromegaly Consensus Group (2020) recommend lanreotide deep subcutaneous injection and octreotide long-acting intramuscular injection as first-line medical therapies for persistent disease after surgery.[7] These updates also recommend Mycapssa for patients who respond to and tolerate injectable lanreotide or octreotide. Signifor LAR is positioned as a second-line therapy due to its increased risk of hyperglycemia. The Pituitary Society Update to

Acromegaly Management Guidelines (2021) recommend a personalized approach to acromegaly medication management, especially for patients who are not surgical candidates or have residual disease.[8] First-line therapies include somatostatin analogs, with Somavert and cabergoline used for resistant or mild cases. Mycapssa offers more convenient options, with treatment tailored to biochemical response, tumor features, and patient preferences.

Supportive Evidence
The American College of Gastroenterology guidelines for diagnosis and management of small bowel bleeding (2015) recommend somatostatin analogs (lanreotide or octreotide long-acting or immediate-release) for the treatment of chronic bleeding due to vascular abnormalities of the gastrointestinal tract.[4] Long-acting somatostatin analogs have been shown as a beneficial rescue therapy to control angiodysplasia bleeding.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of lanreotide products. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with lanreotide products as well as the monitoring required for adverse events and long-term efficacy, approval requires lanreotide products to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

*Indications and/or approval conditions noted with **[EviCore]** are managed by EviCore healthcare for those clients who use EviCore for oncology and/or oncology-related reviews. For these conditions, a prior authorization review should be directed to EviCore at www.EviCore.com.*

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of lanreotide products is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Acromegaly.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient meets ONE of the following (i, ii, or iii):
     - **i.** Patient has had an inadequate response to surgery and/or radiotherapy; OR
     - **ii.** Patient is NOT an appropriate candidate for surgery and/or radiotherapy; OR
     - **iii.** Patient is experiencing negative effects due to tumor size (e.g., optic nerve compression); AND
   - **B)** Patient has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory; AND
     Note: Pre-treatment (baseline) refers to the IGF-1 level prior to the initiation of any somatostatin analog (e.g., Mycapssa [octreotide delayed-release capsules], an octreotide acetate injection product [e.g., Bynfezia Pen, Sandostatin {generics}, Sandostatin LAR Depot], Signifor LAR [pasireotide injection], Somatuline Depot [lanreotide injection], dopamine agonist [e.g., cabergoline, bromocriptine], or Somavert [pegvisomant injection]). Reference ranges for IGF-1 vary among laboratories.

C) The medication is prescribed by or in consultation with an endocrinologist.

Dosing. Approve up to 120 mg administered subcutaneously no more frequently than once every 4 weeks.

---

2. Carcinoid Syndrome. ***[EviCore]*** Approve for 1 year if the medication is prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist.

Dosing. Approve up to 120 mg administered subcutaneously no more frequently than once every 4 weeks.

---

3. Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptides-secreting tumors [VIPomas], insulinomas). ***[EviCore]*** Approve for 1 year if the medication is prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist.

Dosing. Approve up to 120 mg administered subcutaneously no more frequently than once every 4 weeks.

Other Uses with Supportive Evidence

---

4. Pheochromocytoma and Paraganglioma. ***[EviCore]*** Approve for 1 year if the medication is prescribed by or in consultation with an endocrinologist, oncologist, or neurologist.
Dosing. Approve up to 120 mg administered subcutaneously no more frequently than once every 4 weeks.

---

5. Small Bowel Bleeds/Angiodysplasia Related Bleeding. Approve for 6 months if the patient meets BOTH of the following: (A and B):
A) Patient has chronic, recurrent gastrointestinal bleeds lasting ≥ 3 months; AND
B) The medication is prescribed by or in consultation with a gastroenterologist.

Dosing. Approve up to 90 mg administered subcutaneously no more frequently than every 4 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of lanreotide products is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Somatuline® Depot injection [prescribing information]. Basking Ridge, NJ: Ipsen; July 2024.
2. Lanreotide subcutaneous injection [prescribing information]. Warren, NJ: Cipla; September 2024.
3. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 3.2025 – October 1 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed April 2, 2026.

4. Gerson LB, Fidler JL, Cave DR, Leighton JA. ACG clinical guideline: diagnosis and management of small bowel bleeding. *Am J Gastroenterol*. 2015;110(9):1265-1288.
5. Melmed S, di Filippo L, Fleseriu M, et al. Consensus on acromegaly therapeutic outcomes: an update. *Nat Rev Endocrinol*. 2025;21(11):718-737.
6. Katznelson L, Laws ER Jr, Melmed S, et al; Endocrine Society. Acromegaly: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab.* 2014;99:3933-3951.
7. Giustina A, Barkhoudarian G, Beckers A, et al. Multidisciplinary management of acromegaly: A consensus. *Rev Endocr Meta Disord.* 2020;21(4):667-678.
8. Fleseriu M, Biller, BMK, Freda PU, et al. A Pituitary Society update to acromegaly management guidelines. *Pituitary.* 2021; 24:1-13.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	05/15/2024
Selected Revision	For lanreotide subcutaneous, **Carcinoid Syndrome** (FDA-Approved Indication) and **Pheochromocytoma and paraganglioma** (Other Uses with Supportive Evidence) were added as approval conditions. The section of the policy that addressed lanreotide subcutaneous was removed (no longer needed as criteria are now the same for Somatuline Depot and lanreotide subcutaneous).	11/13/2024
Annual Revision	No criteria changes.	05/07/2025
Selected Revision	**Small Bowel Bleeds/Angiodysplasia Related Bleeding:** This condition was added under "Other Uses with Supportive Evidence".	08/27/2025
Annual Revision	No criteria changes.	04/08/2026