

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: 07/22/2026

OVERVIEW

The lanreotide products are somatostatin analogs indicated for the following uses:^{1,2}

- **Acromegaly**, long-term treatment, 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 (GH) and insulin-like growth factor-1 (IGF-1) levels to normal.
- **Carcinoid syndrome**, in adults to reduce the frequency of short-acting somatostatin analog rescue therapy.
- **Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)**, in adults with unresectable, well or moderately differentiated, locally advanced or metastatic GEP-NETs to improve progression-free survival.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for Central Nervous System Cancers (version 2.2026 – June 10, 2026) recommend lanreotide injection as an “Other Recommended” treatment option for GH-secreting sellar tumors (acromegaly) and thyroid-stimulating hormone (TSH)-secreting sellar tumors, for when patients are unable to achieve biochemical control after transsphenoidal pituitary surgery or if there are signs of tumor growth on imaging (category 2A recommendation).³ Approximately 95% of acromegaly cases are caused by GH-secreting sellar tumors (pituitary adenoma).⁴ Hypersecretion of GH levels stimulates IGF-1 production; levels of both GH and IGF-1 are elevated in patients with acromegaly.

The International Acromegaly Consensus Statement (2025) reaffirms somatostatin analogs as the first-line medical therapy for most patients with persistent or non-surgically managed disease, with goals of IGF-1 normalization, symptom control, and tumor growth prevention.⁵ Octreotide injection and lanreotide injection achieve biochemical control in approximately 40% of patients, with dose escalation or increased dosing frequency recommended before switching therapy.

The NCCN guidelines for Neuroendocrine and Adrenal Tumors (version 1.2026 – April 21, 2026) recommend lanreotide injection as a treatment option for the management of carcinoid syndrome; tumors of the gastrointestinal tract, lung, thymus (carcinoid tumors), and pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptide tumors, insulinomas); pheochromocytomas; and paragangliomas (category 2A recommendations).⁶

Supportive Evidence

The American College of Gastroenterology guidelines for diagnosis and management of small bowel bleeding (2015) recommend somatostatin analogs (lanreotide injection, octreotide immediate-release injection, or octreotide long-acting release [LAR] injection) for the treatment of chronic bleeding due to

vascular abnormalities of the gastrointestinal tract.⁷ 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. 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, iii, or iv):
 - 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); OR
 - iv. There are signs of tumor growth on imaging; 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 or oncologist.

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. **Sellar Tumor.** Approve for 1 year if the patient meets BOTH of the following (A and B):
A) Patient has a thyroid-stimulating hormone (TSH)-secreting tumor; AND
B) The medication is prescribed by or in consultation with an oncologist, endocrinologist, or neurosurgeon.

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

6. **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 Central Nervous System Cancers Clinical Practice Guidelines in Oncology (2.2026 – June 10, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on July 15, 2026.
4. Daya R, Seedat F, Purbhoo K, et al. Acromegaly with empty sellar syndrome. *Endocrinol Diabetes Metab Case Rep*. 2021;21-0049.
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. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 1.2026 – April 21, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on July 14, 2026.
7. 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
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
Early Annual Revision	Acromegaly: “There are signs of tumor growth on imaging” was added as an option for approval. In addition, oncologist was added as an option to the specialist requirement. Sellar Tumor: This new condition of approval was added to the policy.	07/22/2026