Drug Coverage Policy

Effective Date 5/1/2026
Coverage Policy Number.....IP0323
Policy Title.....Lanreotide Products

Somatostatin Analogs – Lanreotide Products

- Lanreotide subcutaneous injection – Cipla
- Somatuline® Depot (lanreotide subcutaneous injection – Ipsen, generic)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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.

Coverage Policy

POLICY STATEMENT

Prior Authorization is required for 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.

Certain indications and/or approval conditions that are delegated to EviCore by Evernorth will follow Oncology Medications (1403) coverage policy for prior authorization medical necessity criteria. Note: Any listed preferred product requirements in this coverage policy, inclusive of oncology and/or oncology-related uses, are applicable as noted.

Lanreotide products are considered medically necessary when the following is met:

FDA-Approved Indications

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1. **Acromegaly.** Approve for 1 year if the patient meets ALL of the following (A, B, C and D):
   - **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; AND
   - **C)** The medication is prescribed by or in consultation with an endocrinologist; AND
   - **D)** Preferred product criteria is met for the product(s) as listed in the below table(s)

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

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2. **Carcinoid Syndrome.** Approve for 1 year if the patient meets ALL of the following (A and B):
   - **A)** The medication is prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist; AND
   - **B)** Preferred product criteria is met for the product(s) as listed in the below table(s)

   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).** Approve for 1 year if the patient meets ALL of the following (A and B):
   A) The medication is prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist; AND
   B) Preferred product criteria is met for the product(s) as listed in the below table(s)

   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.** Approve for 1 year if the patient meets ALL of the following (A and B):
   A. The medication is prescribed by or in consultation with an endocrinologist, oncologist, or neurologist; AND
   B. Preferred product criteria is met for the product(s) as listed in the below table(s)

   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 ALL of the following (A, B, and C):
   A) Patient has chronic, recurrent gastrointestinal bleeds lasting ≥ 3 months; AND
   B) The medication is prescribed by or in consultation with gastroenterologist; AND
   C) Preferred product criteria is met for the product(s) as listed in the below table(s)

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

Employer Plans:

Product	Criteria
lanreotide subcutaneous injection (Cipla USA Inc. packager J1932 or NDC: 69097-**0870**-67) Note: Cipla USA Inc. packager, J1930 or NDC 69097-**0906**-67 is the	Patient meets ONE of the following: 1. <u>For Acromegaly</u>, patient has tried one of octreotide ER injectable suspension (Sandostatin LAR Depot, generics), Somatuline Depot or lanreotide acetate (generic) Note: If requesting a Cipla lanreotide product, the preferred product is J1930, NDC 69097-**0906**-67 2. <u>For Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptides-secreting tumors [VIPomas], insulinomas),</u> the following has been met: A. Patient has tried one of octreotide ER injectable suspension (Sandostatin LAR Depot, generics), Somatuline Depot or lanreotide acetate (generic)

Product	Criteria
preferred Cipla product	Note: If requesting a Cipla lanreotide product, the preferred product is J1930, NDC 69097-**0906**-67 3. For Pheochromoctoma/paraganglioma, patient has tried one of octreotide ER injectable suspension (Sandostatin LAR Depot, generics), Somatuline Depot or lanreotide acetate (generic) Note: If requesting a Cipla lanreotide product, the preferred product is J1930, NDC 69097-**0906**-67 4. For Carcinoid syndrome; small bowel bleeds/angiodysplasia related bleeding, the following has been met: A. Patient has tried one Somatuline Depot or lanreotide acetate (generic) Note: If requesting a Cipla lanreotide product, the preferred product is J1930, NDC 69097-**0906**-67

Individual and Family Plans:

Product	Criteria
lanreotide subcutaneous injection (Cipla USA Inc. packager J1932 or NDC: 69097-**0870**-67) Note: Cipla USA Inc. packager, J1930 or NDC 69097-**0906**-67 is the preferred Cipla product	Patient meets ONE of the following: 1. For Acromegaly, patient has tried one of octreotide ER injectable suspension (Sandostatin LAR Depot, generics), Somatuline Depot or lanreotide acetate (generic) Note: If requesting a Cipla lanreotide product, the preferred product is J1930, NDC 69097-**0906**-67 2. For Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptides-secreting tumors [VIPomas], insulinomas), the following has been met: A. Patient has tried one of octreotide ER injectable suspension (Sandostatin LAR Depot, generics), Somatuline Depot or lanreotide acetate (generic) Note: If requesting a Cipla lanreotide product, the preferred product is J1930, NDC 69097-**0906**-67 3. For Pheochromoctoma/paraganglioma, patient has tried one of octreotide ER injectable suspension (Sandostatin LAR Depot, generics), Somatuline Depot or lanreotide acetate (generic) Note: If requesting a Cipla lanreotide product, the preferred product is J1930, NDC 69097-**0906**-67 4. For Carcinoid syndrome; small bowel bleeds/angiodysplasia related bleeding, the following has been met: A. Patient has tried one Somatuline Depot or lanreotide acetate (generic) Note: If requesting a Cipla lanreotide product, the preferred product is J1930, NDC 69097-**0906**-67

Conditions Not Covered

Lanreotide products for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Coding Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J1930	Injection, lanreotide, 1 mg
J1932	Injection, lanreotide, (Cipla), 1 mg

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.

Revision Details

Summary of Changes	Review Date	Effective Date
Acromegaly. **Removed** documentation option of 'Growth hormone suppression testing demonstrating a lack of growth hormone suppression' **Updated** language for preferred product step thru Somatuline Depot **Removed** Thyroid-stimulating hormone (TSH)-secreting pituitary adenoma from policy	6/6/2024	8/15/2024

Added dosing **Added** for lanreotide subcutaneous injection (Cipla USA Inc. packager): step through of Somatuline Depot for Individual and Family Plan **Updated** title from Lanreotide (Non-Oncology Indications)		
Title **Updated** from "Somatostatin Analogs – Lanreotide Products (Non-Oncology Indications)" to "Somatostatin Analogs – Lanreotide Products" **FDA Approved Indications for Oncology Uses** **Added** criteria for: 1) Carcinoid Syndrome, 2) Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptides-secreting tumors [VIPomas], insulinomas) **Other Uses with Supportive Evidence** **Added** criteria for: Pheochromocytoma and Paraganglioma	12/12/2024	2/15/2025
Lanreotide subcutaneous injection. **Added** "J1932 or NDC: 69097-**0870**-67" to lanreotide subcutaneous injection product label **Updated from "**Patient has tried Somatuline Depot" **to "**Patient has tried Somatuline Depot or lanreotide acetate (Cipla USA Inc. packager, J1930] or NDC 69097-**0906**-67"	2/13/2025	4/15/2025
Small bowel bleeds/angiodysplasia related bleeding: The condition small bowel bleeds/angiodysplasia related bleeding was added under "Other Uses with Supportive Evidence".	9/11/2025	11/1/2025
Preferred Product Table. **Updated from** "Patient meets BOTH of the following:Patient has tried Somatuline Depot or lanreotide acetate (Cipla USA Inc. packager, J1930 or NDC 69097-0906-67); AND Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction" **to** "Patient meets ONE of the following: <u>For Acromegaly</u>, patient has tried one of octreotide ER injectable suspension (Sandostatin LAR Depot, generics), Somatuline Depot or lanreotide acetate (generic) Note: If requesting a Cipla lanreotide product, the preferred product is J1930, NDC 69097-0906-67; <u>For Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract,</u>	2/5/2026	4/1/2026

Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptides-secreting tumors [VIPomas], insulinomas), the following has been met: Patient has tried one of octreotide ER injectable suspension (Sandostatin LAR Depot, generics), Somatuline Depot or lanreotide acetate (generic) Note: If requesting a Cipla lanreotide product, the preferred product is J1930, NDC 69097-0906-67; For Pheochromoctoma/paraganglioma, patient has tried one of octreotide ER injectable suspension (Sandostatin LAR Depot, generics), Somatuline Depot or lanreotide acetate (generic). Note: If requesting a Cipla lanreotide product, the preferred product is J1930, NDC 69097-0906-67; For Carcinoid syndrome; small bowel bleeds/angiodysplasia related bleeding, the following has been met: Patient has tried one Somatuline Depot or lanreotide acetate (generic) Note: If requesting a Cipla lanreotide product, the preferred product is J1930, NDC 69097-0906-67"		
No criteria changes	4/16/2026	5/1/2026

The policy effective date is in force until updated or retired.