Drug Coverage Policy

Effective Date 4/15/2025
Coverage Policy Number.....IP0323
Policy Title.....Lanreotide Products

Somatostatin Analogs – Lanreotide Products

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

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.

Cigna Healthcare Coverage Policy

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 2.2024 – August 1, 2024) 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.

Medical Necessity Criteria

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 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.
   - **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 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.
   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 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.
   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.

Employer Plans:

Product	Criteria
lanreotide subcutaneous injection (Cipla USA Inc. packager J1932 or NDC: 69097-**0870**-67)	Patient meets **BOTH** of the following (a and b): a. Patient has tried Somatuline Depot or lanreotide acetate (Cipla USA Inc. packager, J1930 or NDC 69097-**0906**-67); AND b. 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.

Individual and Family Plans:

Product	Criteria
lanreotide subcutaneous injection (Cipla USA Inc. packager J1932 or NDC: 69097-**0870**-67)	Patient meets **BOTH** of the following (a and b): a. Patient has tried Somatuline Depot or lanreotide acetate (Cipla USA Inc. packager, J1930 or NDC 69097-**0906**-67); AND b. 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.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based

literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

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

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

Coding

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 subcutaneous injection [prescribing information]. Basking Ridge, NJ: Ipsen; February 2023.
2. Lanreotide subcutaneous injection [prescribing information]. Warren, NJ: Cipla; September 2023.
3. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 1.2023 – August 2, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 10, 2024.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**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 **Added** dosing	8/15/2024

	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)	
Selected Revision	**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	2/15/2025
Selected Revision	**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"	4/15/2025

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