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: 05/15/2024; selected revision 11/13/2024

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 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.

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

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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.

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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.

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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

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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.

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 2.2024 – August 1, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed November 7, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	08/16/2023
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