Utilization Review Policy 323

POLICY: Somatostatin Analogs – Lanreotide Products Utilization Management Medical Policy
- Lanreotide subcutaneous injection – Cipla

EFFECTIVE DATE: 1/1/2024
LAST REVISION DATE: 8/16/2023

COVERAGE CRITERIA FOR: All UCare Plans

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 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.

Additionally, Somatuline Depot is indicated for **carcinoid syndrome**, in adult patients.[1]

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for **neuroendocrine and adrenal tumors** (version 1.2023 – August 2, 2023) recommend Somatuline Depot 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.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of lanreotide subcutaneous injection is recommended for requests meeting both the preferred product step therapy requirements and indication requirements:

Preferred Product Step Therapy Requirements (New Starts Only)

Criteria. *The patient must meet the following criteria (A or B):*

- **A)** For patients new to lanreotide subcutaneous injection therapy only, must have a trial of Somatuline Depot prior to approval of lanreotide subcutaneous injection. New starts to therapy defined as no use of lanreotide subcutaneous injection within the past 180 days for Medicaid and Commercial patients. New starts to therapy defined as no use of lanreotide subcutaneous injection within the past 365 days for Medicare patients.
- **B)** Patient has a contraindication or other clinical reason why Somatuline Depot cannot be tried before lanreotide subcutaneous injection.

Note: Preferred product step only required for indications FDA-Approved for both lanreotide subcutaneous injection and Somatuline Depot.

FDA-Approved Indications

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1. **Acromegaly.** Approve for 1 year if the patient meets 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 (ULN) 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. **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 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.

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. Lanreotide subcutaneous injection [prescribing information]. Warren, NJ: Cipla; December 2021.
2. 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 August 17, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	New UCare policy with preferred product step therapy for all lines of business.	01/01/2024