BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
1310 G Street, N.W.
Washington, D.C. 20005
202.942.1000
Fax 202.942.1125

5.30.027

Section:	Prescription Drugs	**Effective Date:**	October 1, 2023
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	July 15, 2016
Subject:	Somatuline Depot	**Page:**	1 of 5

Last Review Date: September 8, 2023

Somatuline Depot

Description

Somatuline Depot (lanreotide), Lanreotide

Background
Somatuline Depot/lanreotide is an injectable synthetic analogue of somatostatin, a hormone that regulates the endocrine and neurocrine system. Somatostatin inhibits many downstream hormones, such as those made in the gastrointestinal (GI) tract and pancreas, as well as growth hormone (GH). Because Somatuline Depot mimics somatostatin action, it can be used to treat acromegaly, a condition of excess GH and tumors of the neuroendocrine system (1-4).

Regulatory Status
FDA-approved indications: Somatuline Depot/lanreotide is a somatostatin analog indicated for long-term treatment of acromegalic patients who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy and for the treatment of adult patients with unresectable, well- or moderately- differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival (1-2).

Somatuline Depot is also indicated for the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analogue rescue therapy (1).

Off-Label Uses:
According to current oncology practice guidelines, Somatuline Depot/lanreotide may also be effective in treating the following neuroendocrine tumors (3-4):

- Adrenal gland tumors
- Tumors of the GI tract, lung, and thymus (carcinoid tumors)
- Tumors of the pancreas
- Poorly differentiated (high-grade)/large or small cell tumors

Safety and effectiveness of Somatuline Depot/lanreotide have not been established in pediatric patients (1-2).

Related policies
Bynfezia, Mycapssa, Sandostatin LAR, Signifor LAR

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Somatuline Depot/lanreotide may be considered **medically necessary** if the conditions indicated below are met.

Somatuline Depot/lanreotide may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Acromegaly
    a. Inadequate response or contraindication to surgery or radiotherapy
2. Neuroendocrine tumors (NET)
3. Carcinoid syndrome

AND ONE of the following for Acromegaly or NET **ONLY**:

a. Tumors of the gastrointestinal tract
    i. Member has distant metastases or unresectable disease
b. Thymus tumors
    i. Member has distant metastases or unresectable disease
c. Lung tumors
    i. Member has distant metastases or unresectable disease
d. Pancreatic tumors
    i. Member has distant metastases or unresectable disease
    ii. Somatostatin scintigraphy is positive or has hormone-related symptoms
e. Adrenal gland tumors
    i. Member has a diagnosis of non-adrenocorticotropic hormone (non-ACTH) dependent Cushing's syndrome
    ii. Somatostatin scintigraphy is positive
f. Poorly differentiated (high-grade)/large or small cell tumors (excluding lung)
    i. Member has metastatic or unresectable disease
    ii. Somatostatin scintigraphy is positive or has hormone-related symptoms

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Acromegaly
2. Neuroendocrine tumors (NET)
3. Carcinoid syndrome

AND ONE of the following for Acromegaly or NET **ONLY**:

a. Tumors of the gastrointestinal tract
b. Thymus tumors
c. Lung tumors
d. Pancreatic tumors
e. Adrenal gland tumors
f. Poorly differentiated (high-grade)/large or small cell tumors (excluding lung)

AND the following for **ALL** indications:

a. **NO** disease progression or unacceptable toxicity

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 3 months

Prior – Approval *Renewal* Limits

Duration 12 months

Rationale

Summary

Somatuline Depot/lanreotide is a somatostatin analogue that is used for the treatment of acromegaly due to its inhibition of growth hormone production. Somatuline Depot/lanreotide is also used for treatment of neuroendocrine tumors of the gastrointestinal, adrenal gland, thymus, lung, and pancreas, and poorly differentiated large or small cell NETs to decrease proliferation and prolong progression-free survival. Somatuline Depot is also approved for the treatment of carcinoid syndrome (1-4)

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Somatuline Depot/lanreotide while maintaining optimal therapeutic outcomes.

References

1. Somatuline Depot (lanreotide) [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; February 2023.
2. Lanreotide [package insert]. Warren, NJ: Cipla USA Inc; December 2021.
3. NCCN Clinical Practice Guidelines in Oncology® Neuroendocrine and Adrenal Tumors (Version 2.2022). National Comprehensive Cancer Network, Inc. December 2022. Accessed on August 2, 2023.

4. NCCN Drugs & Biologics Compendium® Lanreotide 2023. National Comprehensive Cancer Network, Inc. Accessed on August 2, 2023.

Policy History

Date	Action
July 2016	Added to PA
September 2016	Annual review
October 2017	Addition of Carcinoid syndrome
December 2017	Annual editorial review
November 2018	Annual review and reference update
December 2019	Annual review and reference update
September 2020	Annual review and reference update
December 2020	Annual review
September 2021	Annual review and reference update
September 2022	Annual review and reference update
October 2022	Addition of branded generic Lanreotide to policy
December 2022	Annual review and reference update
September 2023	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 8, 2023 and is effective on October 1, 2023.