



## Prior Authorization Somatostatin Analogs – Somatuline® Depot (lanreotide injection)

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### Product Identifier(s)

59776

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### National Formulary Medical Necessity

**Cigna covers lanreotide (Somatuline®) as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:**

Prior Authorization is recommended for prescription benefit coverage of Somatuline Depot. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of individuals treated with Somatuline Depot as well as the monitoring required for adverse events and long-term efficacy, approval requires Somatuline Depot to be prescribed by or in consultation with a physician who specializes in the condition being treated.

#### FDA Indication(s)

**1. Acromegaly.** Approve for 1 year if the individual meets the following criteria (A, B, and C):

- A)** Individual meets ONE of the following (i, ii, or iii):
  - i.** Individual has had an inadequate response to surgery and/or radiotherapy; OR
  - ii.** Individual is NOT an appropriate candidate for surgery and/or radiotherapy; OR
  - iii.** Individual is experiencing negative effects due to tumor size (e.g., optic nerve compression); AND

- B)** Individual 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.

- 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.
- 3. Carcinoid Syndrome.** Approve for 1 year if the medication is prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist.

#### Other Uses with Supportive Evidence

- 4. Pheochromocytoma and Paraganglioma.** Approve for 1 year if the medication is prescribed by or in consultation with an endocrinologist, oncologist, or neurologist.

## Conditions Not Covered

Lanreotide (Somatuline®) is considered experimental, investigational or unproven for ANY other use.

## Background

### Overview

Somatuline Depot, a somatostatin analog, is indicated for the following uses:<sup>1</sup>

- **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.
- **Carcinoid syndrome**, in adult patients.
- **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.

### Guidelines

According to the National Comprehensive Cancer Network (NCCN) guidelines for neuroendocrine and adrenal tumors (version 1.2020 – July 10, 2020) 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.<sup>2</sup> 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.

## References

1. Somatuline® Depot injection [prescribing information]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; April 2019.
2. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 1.2020 – July 10, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed July 16, 2020.

## Revision History

Type of Revision	Summary of Changes	Review Date
Annual Revision	<b>Acromegaly.</b> In the Note section referring to the pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level, Mycapssa® (octreotide delayed-release capsules) and octreotide acetate injection products (Bynfezia Pen™, Sandostatin® [generics]) were added as examples of a somatostatin analog.	08/05/2020

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