PRIOR AUTHORIZATION POLICY

POLICY: Somatostatin Analogs – Somatuline® Depot Prior Authorization Policy
- Somatuline Depot (lanreotide injection – Ipsen)

REVIEW DATE: 08/05/2020

OVERVIEW

Somatuline Depot, a somatostatin analog, is indicated for the following uses:[1]

- **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.[2] 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 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 patients 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Somatuline Depot is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Acromegaly.** Approve for 1 year if the patient meets the following criteria (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.

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 RECOMMENDED FOR APPROVAL

Coverage of Somatuline Depot 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 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.