Somatuline Depot

Description

Somatuline Depot (lanreotide)

Background
Somatuline Depot 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 (1-3).

Regulatory Status
FDA-approved indications: Somatuline Depot (lanreotide) Injection is a somatostatin analog indicated for: (1)

1. Long-term treatment of acromegalic patients who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy
2. Treatment of patients with unresectable, well- or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival
3. Treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analogue rescue therapy
Off Label Uses:
According to current oncology practice guidelines, Somatuline Depot may also be effective in treating the following neuroendocrine tumors (2-3):

- 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 have not been established in pediatric patients (1).

Related policies
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 may be considered medically necessary for the treatment of patients age 18 years and older with acromegaly, patients with a neuroendocrine tumor (NET), or patients with carcinoid syndrome and if the conditions indicated below are met.

Somatuline Depot is considered investigational in patients less than 18 years of age and 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)
AND ONE of the following:
   a. Tumors of the Gastrointestinal Tract
      i. Member has distant metastases or unresectable disease

   b. Thymus tumors (carcinoid tumor)
      i. Member has distant metastases or unresectable disease

   c. Lung tumors (carcinoid tumor)
      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-adrenocorticotrophic 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

3. Carcinoid syndrome

Prior – Approval Renewal Requirements

Age 18 years of age or older

Diagnoses

Patient must have ONE of the following:

1. Acromegaly
2. Neuroendocrine tumors:

   **AND ONE** of the following:
   a. Gastrointestinal tract
   b. Thymus
   c. Lung
   d. Pancreas
   e. Adrenal Gland
   f. Poorly Differentiated (high-grade)/Large of Small Cell Tumors (excluding lung)

3. Carcinoid syndrome

   **AND** the following:
   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 medically necessary for the treatment of acromegaly due to its inhibition of growth hormone production. Somatuline Depot is also medically necessary 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. (1-3)
Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Somatuline Depot (lanreotide) while maintaining optimal therapeutic outcomes.

References

Policy History

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<td>July 2016</td>
<td>Added to PA</td>
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<tr>
<td>September 2016</td>
<td>Annual review</td>
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<td>October 2017</td>
<td>Addition of Carcinoid syndrome</td>
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<tr>
<td>December 2017</td>
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<td>November 2018</td>
<td>Annual review and reference update</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.