Lanreotide for Non-Oncology Indications

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Related Coverage Resources

Octreotide for Non-Oncology Indications
Oncology Medications

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document (Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document) may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Coverage Policy

This coverage policy addresses the use of lanreotide (Somatuline® Depot) for non-oncology indications. The use of lanreotide (Somatuline® Depot) for oncology indications is addressed in a separate coverage policy. Please refer to the related coverage policy link above (Oncology Medications).

Lanreotide injection (Somatuline® Depot) is considered medically necessary when ONE of the following criteria is met:

- Treatment of acromegaly and **either** of the following:
  - Individual has had an inadequate response to surgery and/or radiotherapy
  - Individual is not a candidate for surgery and/or radiotherapy
- Treatment of pituitary adenoma producing thyroid stimulating hormone (TSH) when surgical resection has been incomplete

Initial authorization is up to 12 months.

Lanreotide (Somatuline® Depot) is considered medically necessary for continued use when ALL of the following criteria are met:

- Pre-treatment clinical condition met the initial criteria
• Individual has had a positive clinical response

Reauthorization is up to 12 months

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Lanreotide (Somatuline® Depot) is considered experimental, investigational or unproven for ANY other use including the following:
• Autosomal dominant polycystic kidney disease (ADPKD)
• Malignant inoperable bowel obstruction
• Polycystic liver disease

Note: Receipt of sample product does not satisfy any criteria requirements for coverage

FDA Approved Indications

FDA Approved Indications
Acromegaly
Somatuline Depot is indicated for the long-term treatment of acromegalic 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 (GH) and insulin growth factor-1 (IGF-1) levels to normal

Gastroenteropancreatic Neuroendocrine Tumors
Somatuline Depot is indicated 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.

Carcinoid Syndrome
Somatuline Depot is indicated for the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.

Recommended Dosing

FDA Recommended Dosing
Acromegaly
Somatuline Depot is intended for administration by a healthcare provider. The recommended starting dosage of Somatuline Depot is 90 mg given via the deep subcutaneous route, at 4-week intervals for 3 months.
After 3 months the dosage may be adjusted as follows:
• GH >1 to ≤ 2.5 ng/mL, IGF-1 normal and clinical symptoms controlled: maintain Somatuline Depot dose at 90 mg every 4 weeks.
• GH > 2.5 ng/mL, IGF-1 elevated and/or clinical symptoms uncontrolled, increase Somatuline Depot dose to 120 mg every 4 weeks.
• GH ≤ 1 ng/mL, IGF-1 normal and clinical symptoms controlled: reduce Somatuline Depot dose to 60 mg every 4 weeks.

Thereafter, the dose should be adjusted according to the response of the patient as judged by a reduction in serum GH and/or IGF-1 levels; and/or changes in symptoms of acromegaly.
Patients who are controlled on Somatuline Depot 60 mg or 90 mg may be considered for an extended dosing interval of Somatuline Depot 120 mg every 6 or 8 weeks. GH and IGF-1 levels should be obtained 6 weeks after this change in dosing regimen to evaluate persistence of patient response.

Continued monitoring of patient response with dose adjustments for biochemical and clinical symptom control, as necessary, is recommended.

The starting dose in patients with moderate and severe renal or moderate and severe hepatic impairment should be 60 mg via the deep subcutaneous route, at 4 week intervals for 3 months followed by dose adjustment as described above.

**Gastroenteropancreatic Neuroendocrine Tumors**
The recommended dose of Somatuline Depot is 120 mg administered every 4 weeks by deep subcutaneous injection. There is no recommended dose adjustment for mild or moderate renal impairment. There is insufficient information to recommend a dose for patients with severe renal impairment or with hepatic impairment of any severity.

**Carcinoid Syndrome**
The recommended dosage of Somatuline Depot is 120 mg administered every 4 weeks by deep subcutaneous injection. If patients are already being treated with Somatuline Depot for GEP-NETs, do not administer an additional dose for the treatment of carcinoid syndrome.

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**Disease Overview**
Acromegaly is a rare, life-shortening disorder, with a prevalence estimated at 40 to 125 cases per million persons and an annual incidence of 3 to 4 new cases per million each year. Acromegaly is generally diagnosed in patients 40 to 50 years of age, but can occur in patients at any age. Most often, it is caused by GH over-secretion from a benign tumor on the pituitary gland, a somatotroph adenoma (≥ 95% of cases). An increase in IGF-1 production by the liver accompanies the increase in GH. Somatotroph adenomas are slow growing and therefore, diagnosis is hampered by the slow, insidious onset of the disease. Reports suggest that the mean time from symptom onset to acromegaly diagnosis is 3 to 7 years. The clinical manifestation of acromegaly range from subtle signs of enlargement of the extremities, soft tissue swelling, arthralgias, jaw prognathism, fasting hyperglycemia, and hyperhidrosis to “florid” osteoarthritis, frontal bone bossing, diabetes mellitus, hypertension, and respiratory and cardiac failure. GH-secreting somatotroph adenomas that occur in young patients before closure of the epiphyses result in accelerated growth and gigantism. (Melmed, 2006) Hypersecretion of GH and IGF-1 over time can have multiple deleterious effects, including cardiovascular complications, impaired glucose tolerance/diabetes, hypertension, respiratory conditions, and colorectal tumors. (Oberg, 2016) Mortality is increased in patients with acromegaly (mortality ratios approximately 1.3 to 1.9 relative to the general population; comorbidities may increase this ratio). Surgical resection of the tumor is generally the first-line therapy for acromegaly and results in disease control in approximately 60% of patients. However, radiotherapy (RT) and medications, including somatostatin analogs, Somavert® (pegvisomant for injection), and cabergoline, are also used to manage this condition. As adjuvant therapy, somatostatin analogs are estimated to normalize IGF-1 levels in approximately 17% to 35% of patients. (Katznelson, 2014)

**Professional Societies/Organizations**

**The Endocrine Society**
The Endocrine Society Clinical Practice Guidelines for Acromegaly (2014) recommend transsphenoidal surgery as the primary therapy in most patients; repeat surgery may be considered in patients with residual intrasellar disease after initial surgery. Although routine preoperative medical therapy is not recommended, patients with severe pharyngeal thickness and sleep apnea or high-output heart failure may receive therapy with a somatostatin analog preoperatively to reduce surgical risk from severe comorbidities. A somatostatin analog may be used as primary therapy in patients who cannot be cured by surgery; have extensive cavernous sinus invasion; do not have chiasmal compression; or are poor surgical candidates. For patients with persistent
disease after surgery, Somatuline Depot, along with other somatostatin analogs, is recommended as an effective therapy. In some cases, additional medical therapy and/or radiotherapy may be needed. (Katznelson, 2014)

**The American Board of Internal Medicine’s (ABIM) Foundation Choosing Wisely® Initiative:**
No recommendations are available for Lanreotide injection (Somatuline® Depot).

**Centers for Medicare & Medicaid Services - National Coverage Determinations (NCDs)**
There are no CMS National Coverage Determinations for Lanreotide injection (Somatuline® Depot).

**Other Covered Uses**

**Pheochromocytoma/Paraganglioma**
The NCCN guidelines on neuroendocrine and adrenal tumors, recommend octreotide or lanreotide as a second-line therapy for symptom control of local, unresectable pheochromocytomas or paragangliomas. (NCCN, 2019) Please refer to the related coverage policy link above (Oncology Medications).

**Pituitary adenoma producing thyroid stimulating hormone**
An open, non-comparative, multi-center trial evaluated use of lanreotide 30 mg every 10-14 days in 18 patients with a thyroid stimulating hormone (TSH)-secreting pituitary adenoma. Fifteen patients had failed previous pituitary surgery, additional radiotherapy, or medical therapy. Administration of lanreotide resulted in an improvement in clinical signs of hyperthyroidism; decreases in TSH, free T4, and free T3 levels; and in no statistically significant change in adenoma size. Treatment was well-tolerated with side effects reported as pain at injection site, abdominal cramps, and diarrhea. (Kuhn, 2000)

AHFS Drug Information 2020 Edition does not support any off-label uses of lanreotide (Somatuline® Depot)

**Experimental, Investigational, Unproven Uses**
Randomized controlled trials have investigated use of lanreotide, without conclusive benefit, for autosomal dominant polycystic kidney disease (ADPKD) (Meijer, 2014), malignant inoperable bowel obstruction (Mariani, 2012) and polycystic liver disease. (Temmerman, 2013)

**Coding/ Billing Information**

**Note:**
1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

**Covered when medically necessary:**

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tr>
<td>J1930</td>
<td>Injection, lanreotide, 1 mg</td>
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**References**