



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject Lanreotide Injection
(Somatuline® Depot)**

Effective Date 2/15/2011
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Coverage Policy Number 9005

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Hyperlink to Related Coverage Policies

Octreotide (Sandostatin[®], Sandostatin LAR[®]
Depot)

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), 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 supercedes** 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. Proprietary information of CIGNA. Copyright ©2011 CIGNA

Coverage Policy

CIGNA covers lanreotide injection (Somatuline® Depot) as medically necessary for the long-term treatment of acromegaly for EITHER of the following indications:

- inadequate response to surgery and/or radiotherapy
- surgery and/or radiotherapy are not an option

FDA Approved Indications

Somatuline Depot (lanreotide) injection is a somatostatin analog indicated for the long-term treatment of acromegalic patients who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy.

FDA Recommended Dosing

The recommended dose range is 60 mg to 120 mg every 4 weeks as an injection. The recommended dose is 90 mg every 4 weeks for 3 months. Adjust thereafter based on GH and/or IGF-1 levels. For renal and hepatic impairment, the initial dose is 60 mg every 4 weeks for 3 months in moderate and severe renal or hepatic impairment. Adjust thereafter based on GH and/or IGF-1 levels.

Drug Availability

Somatuline Depot is supplied in strengths of 60 mg, 90 mg, and 120 mg in a single, sterile, prefilled, ready-to-use, polypropylene syringe fitted with a 20 mm needle covered by a dry natural rubber sheath. Each prefilled syringe is sealed in a laminated pouch and packed in a carton.

General Background

Pharmacology

Lanreotide is a synthetic analog of somatostatin. Octreotide is the only other synthetic somatostatin analog marketed in the United States and is also available as a once monthly depot injection (Sandostatin LAR Depot) as well. Lanreotide decreases GH and IGF-I release via high affinity binding and agonistic activity on human somatostatin receptors (SSTR) 2 and 5 and has multiple effects on meal-time physiology. Lanreotide depot is believed to precipitate upon deep subcutaneous injection, forming a drug reservoir in the tissue. Total bioavailability ranges from 69.0 – 78.4%. Steady state peak concentrations range from 3.8 – 7.7 ng/mL while 28-day trough levels range from 1.8 – 3.8 ng/mL. The elimination half-life of lanreotide depot is 23 – 30 days and excretion is thought to be largely biliary. Patients with moderate to severe renal and hepatic impairment experience an increase in drug exposure.

Clinical Efficacy

There is a single published, randomized trial comparing lanreotide depot injection to octreotide in acromegaly patients. Lanreotide depot 120 mg injected every 4 weeks was compared to octreotide injectable suspension 30 mg given every 4 weeks. After 6 months, GH and IGF-I decreased similar amounts in both treatment groups. Response rates and p values were not reported. Published case series reported similar results in patients who changed from octreotide injectable suspension to lanreotide depot injection.

Adverse Reactions

The most common adverse effects of lanreotide depot injection are diarrhea, abdominal pain, nausea, constipation, flatulence, vomiting, cholelithiasis and injection site reactions. Serious adverse effects include bradycardia, hypertension, and anemia. Somatostatin analogs appear to decrease clearance of drugs metabolized by CYP450 enzymes in the liver. Use drugs that have a low therapeutic index and are metabolized mainly by CYP3A4 (eg. quinidine and terfenadine) with caution in patients taking lanreotide. The gastrointestinal effects of lanreotide may result in decreased absorption of other medications (eg. cyclosporin).

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

| HCPCS Codes | Description |
|-------------|-----------------------------|
| J1930 | Injection, Lanreotide, 1 mg |

| ICD-9-CM Diagnosis Codes | Description |
|--------------------------|--------------------------|
| 253.0 | Acromegaly and gigantism |

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