

Prior Authorization DRUG Guidelines

SOMATULINE DEPOT (Lanreotide)

Effective Date: 1/28/14

Date Developed: 1/28/14 by Catherine Sanders, MD

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(Archived 1/22/19)

Somatuline is a synthetic octapeptide analogue of somatostatin which is a peptide inhibitor of multiple endocrine, neuroendocrine, and exocrine mechanisms. Displays a greater affinity for somatostatin type 2 (SSTR2) and type 5 (SSTR5) receptors found in pituitary gland, pancreas, and growth hormone (GH) secreting neoplasms of pituitary gland and a lesser affinity for somatostatin receptors 1, 3, and 4. Reduces GH secretion and also reduces the levels of insulin-like growth factor 1.

Pre-Authorization Criteria: long term treatment of acromegaly in patients who are not candidates for or are unresponsive to surgery and/or radiotherapy; treatment of unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic tumors (GEP-NET tumors; 120 mg strength only, see below)

Dosing: Adult:

Acromegaly: Adults (per U.S. labeling) or Children ≥ 16 years and Adults (per Canadian labeling): SubQ: 90 mg once every 4 weeks for 3 months; after initial 90 days of therapy, adjust dose based on clinical response of patient, growth hormone (GH) levels, and/or insulin-like growth factor 1 (IGF-1) levels as follows:

GH ≤ 1 ng/mL, IGF-1 normal, symptoms stable: 60 mg once every 4 weeks; once stabilized on 60 mg every 4 weeks, may consider regimen of 120 mg every 6-8 weeks (extended-interval dosing)

GH >1 -2.5 ng/mL, IGF-1 normal, symptoms stable: 90 mg once every 4 weeks; once stabilized on 90 mg every 4 weeks, may consider regimen of 120 mg every 6-8 weeks (extended-interval dosing)

GH >2.5 ng/mL, IGF-1 elevated and/or uncontrolled symptoms: 120 mg once every 4 weeks

GEP-NET tumors: dosing restricted to 120 mg once every 4 weeks, deep subcutaneous injection

Dosing: Pediatric:

Acromegaly: Children ≥ 16 years (*Canadian labeling*): Refer to adult dosing.

Dosing: Geriatric:

Refer to adult dosing.

Dosing: Renal Impairment:

U.S. labeling: Moderate-to-severe impairment: Recommended starting dose: 60 mg; use of an extended-interval dose of 120 mg every 6-8 weeks should be done with caution.

Dosing: Hepatic Impairment:

U.S. labeling: Moderate-to-severe impairment: Recommended starting dose: 60 mg; use of an extended-interval dose of 120 mg every 6-8 weeks should be done with caution.

Dosage Forms: U.S.:

Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Solution, Subcutaneous:

Somatuline Depot: 120 mg/0.5 mL (0.5 mL); 60 mg/0.2 mL (0.2 mL); 90 mg/0.3 mL (0.3 mL)

Generic Equivalent Available: U.S.-No

Administration:

Administer by deep subcutaneous injection into superior outer quadrant of buttocks. Do not fold skin. Alternate injection sites.

Adverse Reactions:

10%: bradycardia, diarrhea, abdominal pain, flatulence, nausea, weight loss

Other Serious Less Common Reactions: cholelithiasis, gallbladder sludge, hyperglycemia, hypoglycemia, hypothyroidism, bradycardia, hypertension, anemia.

References:

1. Caron P, Beckers A, Cullen DR, et al, "Efficacy of the New Long-Acting Formulation of Lanreotide (Lanreotide Autogel) in the Management of Acromegaly," *J Clin Endocrinol Metab*, 2002, 87(1):99-104. [PubMed [17489310](#)]
2. Chandrachar E and Arulkumaran S, "Pituitary and Adrenal Disorders Complicating Pregnancy," *Curr Opin Obstet Gynecol*, 2003, 15(2):101-6. [PubMed [12634600](#)]
3. Melmed S, Casanueva FF, Klibanski A, et al, "A Consensus on the Diagnosis and Treatment of Acromegaly Complications," *Pituitary*, 2012, Aug 18. [PubMed [22903574](#)]
4. Rasmussen E, Eriksson B, Oberg K, et al, "Selective Effects of Somatostatin Analogs on Human Drug-Metabolizing Enzymes," *Clin Pharmacol Ther*, 1998, 64(2):150-9. [PubMed [9728895](#)]
5. Reubi JC, Waser B, Schaer JC, et al, "Somatostatin Receptor sst1-sst5 Expression in Normal and Neoplastic Human Tissues Using Receptor Autoradiography With Subtype-Selective Ligands," *Eur J Nucl Med*, 2001, 28(7):836-46. [PubMed [11504080](#)]
6. www.uptodate.com: Lanreotide: Drug Information
7. www.epocrates.com: Somatuline Drug information

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