



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: lanreotide

Brand Name: Somatuline® Depot

Medication Class: somatostatin analog

FDA Approved Uses: treatment of acromegaly in patients who have failed or are not candidates for surgery or radiation

Available Dosage Forms: prefilled syringe of extended release injection solution: 60mg, 90mg, 120mg

Usual Dose: Initiate therapy with 90 mg deep gluteal SQ injection every 4 weeks for 3 doses, then adjust dose based on patients' GH (growth hormone) and IGF-1 (insulin-like growth factor 1) levels. Use a starting dose of 60 mg in patients with moderate to severe renal or hepatic impairment.

- At 3 months, adjust as follows (regardless of initial dose):
 - GH > 2.5 ng/mL, IGF-1 elevated, and/or clinical symptoms are uncontrolled: 120 mg every 4 weeks
 - GH > 1 to ≤ 2.5 ng/mL, IGF-1 normal, and clinical symptoms are controlled: 90 mg every 4 weeks
 - GH ≤ 1 ng/mL, IGF-1 normal, and clinical symptoms are controlled: 60 mg every 4 weeks

Duration of Therapy: Indefinite; long-term

Approximate monthly cost (based on AWP 2008): 60mg- 120mg every 4 weeks:
60mg = \$1800, 90 mg = \$2330, 120mg = \$3440

Criteria for Use: *(bullet points below are all inclusive unless otherwise noted)*

- Clinically diagnosed acromegaly
- Failure to respond to surgery or radiation **OR** not a candidate for surgery or radiation

Cautions:

- Can reduce gallbladder motility, leading to gallbladder sludge and cholelithiasis
- Can cause dysglycemias: hypoglycemia, hyperglycemia, diabetes
- Can cause bradycardia
- Initiate at 60 mg in moderate to severe renal or hepatic impairment

Monitoring:

- GH level, with goal GH level ≤ 2.5 ng/mL
- IGF-1 level, with goal of age & gender normalization of IGF-1



Contraindications:

- None

Not Approved if:

- Patient does not meet the above-stated criteria

Special Considerations:

- Store in refrigerator at 2°C to 8°C; warm at room temperature for 30 minutes before injection
- Depot somatostatin analogs are recommended as first line pharmacotherapy in the American Association of Clinical Endocrinologists’ current acromegaly treatment guidelines; the guidelines do not give preference to either octreotide or lanreotide
- Prefilled syringes do not require assembly or mixing; coupled with smaller injection volume and shorter needle, lanreotide could reduce the injection burden and offer increased outpatient management of acromegaly
- Needle is covered by a natural rubber sheath → may be a consideration in patients with latex allergies, though literature does not allude to this
- Limited clinical comparisons to octreotide depot injection: no head-to-head comparisons, only cross-over studies with patients previously treated with octreotide depot
 - Cross-over studies show similar efficacy and similar degrees of GH and IGF-1 suppression between octreotide and lanreotide depot injections, but fewer injection site reactions with lanreotide depot
 - Intolerance (severe diarrhea or GI upset; rash) to octreotide does not necessarily mean intolerance to lanreotide → so, an option for octreotide-intolerant patients
- Despite depot dosage form, peak serum levels are attained within first day following injection
- Also marketed outside the US for stabilizing growth of carcinoid neuroendocrine tumors and reducing associated symptoms
- FDA classifies the treatment of acromegaly as an orphan indication (orphan drugs treat illnesses that afflict <200,000 patients in the US)

Comparison of available long-acting injectable somatostatin analogs					
Somatostatin Analog	How supplied	How injected	Dosing interval	Monthly Dose	Price per Dose
Lanreotide (Somatuline® Depot)	<ul style="list-style-type: none"> • Ready-to-use prefilled syringes of < 0.5 mL • Allows at-home administration 	<ul style="list-style-type: none"> • SQ injection • Short 20 mm needle 	Q4 weeks	60 mg	\$2052.00
				90 mg	\$2481.60
				120 mg	\$3668.40
Octreotide (Sandostatin® LAR Depot)	<ul style="list-style-type: none"> • Kits for reconstitution of ~2.5 mL • Requires healthcare professional for injection 	<ul style="list-style-type: none"> • IM injection • Longer 38 mm needle for muscle penetration 	Q4 weeks	10 mg	\$1866.29
				20 mg	\$2335.79
				30 mg	\$3453.07



Efficacy of long-acting injectable somatostatin analogs					
Treatment		Timepoint	Percent of patients with...		
			GH \leq 2.5 ng/mL	Normal IGF-1	GH \leq 2.5 ng/mL + Normal IGF-1
Sandostatin® LAR Depot	Trial 1 (n=88)	44 weeks	66%	67%	57%
	Trial 2 (n=122)	108 weeks	47%	51%	42%
Somatuline® Depot	Trial 1 (n=107)	Baseline	0%	8%	0%
		4 weeks	34%	25%	16%
		16 weeks	50%	55%	39%
		32 weeks	57%	55%	45%
		52 weeks	54%	59%	43%
	Trial 2 (n=63)	Baseline	33%	0%	0%
		12 weeks	75%	27%	22%
		28 weeks	80%	37%	34%
48 weeks		86%	43%	38%	

P&T Approval: _____ Date: _____