

When requesting Somatuline® Depot (lanreotide injectable) for non-oncology indication(s), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Non-oncology indication

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

Coverage Guidelines

Acromegaly

The patient must meet ONE of the following (A of B):

A) Initial Therapy: The patient meets ALL of the following criteria (i, ii, and iii):

- i) The patient meets ONE of the following criteria (a, b, and c):
 - a) The patient has had an inadequate response to surgery and/or radiotherapy;
OR
 - b) The patient is not an appropriate candidate for surgery and/or radiotherapy;
OR
 - c) The patient is experiencing negative effects due to tumor size (e.g., optic nerve compression); AND
- ii) The medication is prescribed by or in consultation with an endocrinologist; AND
- iii) The patient has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal (ULN) based on age and gender of the reporting laboratory.

B) Patient is Currently Receiving Somatuline Depot: The patient has responded to Somatuline Depot (e.g., decrease/normalization of IGF-1 level, decrease in growth hormone level, improvement in metabolic abnormalities [e.g., diabetes mellitus]), as determined by the prescriber.

Approval Duration (initial): 3 months

Approval Duration (renewal): 12 months

Dosing Recommendations

- The recommended initial dose is 90 mg given via the deep subcutaneous (SC) route at 4-week intervals for 3 months.
- The dose may be increased to 120 mg SC every 4 weeks or 60 mg SC every 4 weeks in patients who have elevated or reduced GH and/or age and sex adjusted IGF-1 levels, respectively. Dose adjustments based on specific GH/IGF-1 levels are in the prescribing information.
- 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.

References

1. Somatuline® Depot for injection [prescribing information]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; September 2017.
2. Katznelson L, Laws ER Jr, Melmed S, et al; Endocrine Society. Acromegaly: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2014; 99:3933-3951.