

Somatuline[®] Depot (lanreotide injectable)

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

FDA-Approved Non-Oncology Indication

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.

Coverage Guidelines

Acromegaly

The individual must meet following criteria for approval:

- Had an inadequate response to surgery and/or radiotherapy **OR**
- Is not an appropriate candidate for surgery and/or radiotherapy **OR**
- Is experiencing negative effects due to tumor size (e.g., optic nerve compression) **AND**
- Has/had a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory **AND**
- Somatuline Depot is prescribed by or in consultation with an endocrinologist

Approval Duration: 12 months

Dosing Recommendations

The recommended starting dose is 90 mg every 4 weeks for 3 months. Dose should be adjusted thereafter based on growth hormone and/or IGF-1 levels.

After 3 months, the dosage may be adjusted as follows:

- GH greater than 1 ng/mL to less than or equal to 2.5 ng/mL, IGF-1 normal, and clinical symptoms controlled: maintain Somatuline Depot dosage at 90 mg every 4 weeks.
- GH greater than 2.5 ng/mL, IGF-1 elevated, and/or clinical symptoms uncontrolled: increase Somatuline Depot dosage to 120 mg every 4 weeks.
- GH less than or equal to 1ng/mL, IGF-1 normal, and clinical symptoms controlled, reduce Somatuline Depot dosage to 60 mg every 4 weeks.
- 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.