

Somatuline® Depot (lanreotide injectable)

When requesting 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

Lanreotide is indicated for the long-term treatment of acromegaly in individuals 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 **all** of the following criteria for approval:

- Meets one of the following:
 - o Had an inadequate response to surgery and/or radiotherapy;
 - o Is not an appropriate candidate for surgery and/or radiotherapy;
 - o Is experiencing negative effects due to tumor size (e.g., optic nerve compression);
- 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;
- Lanreotide 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 lanreotide dosage at 90 mg every 4 weeks.
- GH greater than 2.5 ng/mL, IGF-1 elevated, and/or clinical symptoms uncontrolled: increase lanreotide dosage to 120 mg every 4 weeks.
- GH less than or equal to 1ng/mL, IGF-1 normal, and clinical symptoms controlled, reduce lanreotide dosage to 60 mg every 4 weeks.
- Patients who are controlled on lanreotide 60 mg or 90 mg may be considered for an extended dosing interval of lanreotide 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 injection [prescribing information]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; February 2023.
2. Lanreotide subcutaneous injection [prescribing information]. Warren, NJ: Cipla; December 2021.