

Lanreotide (Somatuline® Depot, generic) Injection

When requesting lanreotide injection (Somatuline Depot, generic) for non-oncology indication, the individual requiring treatment must be diagnosed with the following FDA-approved indication or the off-label compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Non-Oncology Indication

Lanreotide is indicated for the treatment of acromegaly in individuals who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy are not an option.

Approved Off-label Use

- Small Bowel Bleeds/Angiodysplasia Related Bleeding

Coverage Guidelines

Acromegaly

The individual must meet **all** of the following criteria for approval:

- Meets one of the following:
 - 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);
- 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

Small bowel bleeds/Angiodysplasia related bleeding

The individual must meet both of the following criteria for approval:

- Has chronic, recurrent gastrointestinal bleeds lasting 3 months or longer;
- Lanreotide is prescribed by or in consultation with a gastroenterologist.

Approval Duration: 6 months

Dosing Recommendation

Acromegaly

The recommended dose is up to 120 mg administered subcutaneously no more frequently than once every 4 weeks.

Small bowel bleeds/Angiodysplasia related bleeding

The recommended dose is up to 90 mg administered subcutaneously no more frequently than once every 4 weeks.

References

1. Somatuline® Depot injection [prescribing information]. Basking Ridge, NJ: Ipsen; July 2024.
2. Lanreotide subcutaneous injection [prescribing information]. Warren, NJ: Cipla; September 2024.
3. Gerson LB, Fidler JL, Cave DR, Leighton JA. ACG clinical guideline: diagnosis and management of small bowel bleeding. *Am J Gastroenterol*. 2015;110(9):1265-1288.