

Somatuline[®] Depot (lanreotide)



When requesting Somatuline[®] Depot(lanreotide), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved indications¹

- Somatuline[®] Depot (lanreotide) 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.
- Somatuline[®] Depot (lanreotide) is indicated for the treatment of individuals with unresectable, well- or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors to improve progression-free survival*.

*Oncology-related label uses are addressed in the Medical Oncology program.

Approved Off-label Compendial use²

- No off-label uses meet evidence standards*

*Oncology-related off-label uses are addressed in the Medical Oncology program.

Coverage Guidelines

Acromegaly

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

- Clinical evidence of acromegaly¹ (e.g., frontal bossing, coarse facial features, thick lips, protruding jaw with widely spaced teeth, large hands and feet, etc.)³
- The individual has a high pretreatment IGF-1 level for age and/or gender³
- The individual is not a candidate for pituitary surgery or has had surgery that was not curative^{1,3}

For reauthorization:

- Must meet above criteria and must show IGF-1 level has decreased or normalized while on therapy^{1,3}

Approval duration: 12 Months

Additional Information for Prescribers¹

Our prescribers are alerted to the following safety concerns as educational points/reminders:

- Monitor individuals for gallstone formation due to reduced gallbladder motility.
- Individuals treated with Somatuline[®] Depot (lanreotide) may experience hypoglycemia or hyperglycemia. Monitor blood glucose levels when treatment is initiated or when the dose is altered, and antidiabetic treatment should be adjusted accordingly.
- Thyroid function tests are recommended where clinically indicated.

- Drugs mainly metabolized by CYP3A4 and which have a narrow therapeutic index (e.g., quinidine, terfenadine) should be monitored appropriately.
- Somatuline® Depot (lanreotide) may lead to a decrease in heart rate in individuals without underlying cardiac disease. In individuals with cardiac disorders, sinus bradycardia may occur. Use with caution in at-risk individuals.

References

1. Somatuline® Depot prescribing information. Signes, France: Ipsen Biopharmaceuticals, Inc.: December 2014.
2. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed February 21, 2017. <https://www.micromedexsolutions.com>.
3. Katzmeyer L, Atkinson J, Cook D, et al. American Association of Endocrinologists Medical Guidelines for Clinical Practice for the Diagnosis and Treatment of Acromegaly. *Endocrine Practice*. 2011;17:4. Accessed February 21, 2017. <https://www.aace.com/files/acromegaly-guidelines.pdf>.