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Lanreotide

(Somatuline Depot®) J1930 (1 mg)

Covered with prior authorization

Requests for Somatuline Depot® (lanreotide) may be approved if the following criteria are met:

- Individual has a diagnosis of acromegaly; **AND**
- Either of the following:
    - Individual has had an inadequate response to surgery and/or radiotherapy; **OR**
    - Surgery and/or radiotherapy are not an option (such as but not limited to, individual is an inappropriate candidate for surgical- or radiation-based therapy);

  OR
- Individual has a diagnosis of unresectable, well-or moderately-differentiated, locally advanced or metastatic Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs) (Label, NCCN 2A);
  OR
- Individual has a diagnosis of carcinoid syndrome;
  OR
- Individual has a diagnosis of Neuroendocrine Tumors, including GI Tract, Lung, Thymus, Pancreas, and Pheochromocytoma/Paraganglioma (NCCN 2A) and used in one of the following ways:
    - To treat unresectable primary gastrinoma; **OR**
    - For treatment of symptoms related to hormone hypersecretion and/or carcinoid syndrome; **OR**
    - For tumor control in patients with unresectable, locally advanced, and/or metastatic disease.

Requests for Somatuline Depot® (lanreotide) may **not** be approved if the above criteria are not met and for all other indications not included above.

Initial and renewal authorizations are for up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

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Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Exclusion criteria:

- Somatuline Depot® (lanreotide)may not be approved when the above criteria are not met and for all other indications.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage. Somatuline Depot® is also FDA approved for the treatment of gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression free survival and carcinoid syndrome to reduce the frequency of short-acting somastatin analog rescue therapy. Somatuline Depot® is provided as a single dose, prefilled syringe and administered as a deep subcutaneous injection. Somatuline Depot® may reduce gallbladder motility and lead to gallstone formation. Some may also experience hypoglycemia or hyperglycemia as a result of inhibition of the secretion of insulin and glucagon. The most common overall cardiac adverse reactions observed included sinus bradycardia, bradycardia, and hypertension.

Key References Accessed 8/2022:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
5. The NCCN Drugs & Biologics Compendium (NCCN Compendium™) © 2021 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically.
    a. Neuroendocrine and Adrenal Tumors V1.2021.

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Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.