Somatuline Depot (lanreotide)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Somatuline Depot (lanreotide) 60 mg/0.2 mL, 90 mg/0.3 mL, 120 mg/0.5 mL prefilled syringe	1 syringe per 28 days*

*Individual should not receive more than 120 mg combined every four (4) weeks by any provider for the diagnoses of acromegaly, carcinoid syndrome, gastroenteropancreatic neuroendocrine tumor.

APPROVAL CRITERIA

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

I. Individual has a diagnosis of acromegaly; **AND**
II. Diagnosis of acromegaly has been confirmed by, or in consultation with, a board-certified endocrinologist who has reviewed and verified the test results (including but not limited to: Insulin-like Growth Factor 1 levels; Oral Glucose Tolerance Test with associated Growth Hormone (GH) levels) that are indicative of a positive test; **AND**
III. Either of the following:
    A. Individual has had an inadequate response to surgery and/or radiotherapy; **OR**
    B. 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
IV. Individual has a diagnosis of unresectable, well-or moderately-differentiated, locally advanced or metastatic Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs) (Label, NCCN 2A);

OR
V. Individual has a diagnosis of carcinoid syndrome;

OR
VI. 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:
    A. To treat unresectable primary gastrinoma; **OR**
    B. For symptomatic treatment of insulinoma tumors expressing somatostatin receptors; **OR**

C. For symptomatic treatment of glucagonoma; **OR**
D. symptomatic treatment of tumors secreting vasoactive intestinal polypeptide (VIPoma); **OR**
E. For treatment of symptoms related to hormone hypersecretion and/or carcinoid syndrome; **OR**
F. For tumor control in patients with unresectable, locally advanced, and/or metastatic disease **OR**
G. Individual is diagnosed with diffuse idiopathic pulmonary neuroendocrine cell hyperplasia (DIPNECH).

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. 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. Accessed: July 8, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. The NCCN Drugs & Biologics Compendium (NCCN Compendium™) © 2022 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically.
    a. Neuroendocrine and Adrenal Tumors V1.2022. Revised May 23, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.