Medical Drug Clinical Criteria

Subject:	Somatuline Depot (lanreotide)		
Document #:	CC-0142	**Publish Date:**	~~09/18/2023~~10/23/2023
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Overview

This document addresses the use of Somatuline Depot (lanreotide) for acromegaly. 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 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. Somatuline Depot is provided as a single dose, prefilled syringe and administered as a deep subcutaneous injection.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Somatuline Depot (lanreotide)

Requests for 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~~ verified by, or in consultation with, a board-certified endocrinologist who has reviewed and verified the test results (~~such as~~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).

Somatuline Depot (lanreotide) may not be approved when the above criteria are not met and for all other indications.
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Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J1930	Injection, lanreotide, 1 mg [Somatuline Depot]
J1932	J1932-Injection, lanreotide, (cipla), 1 mg

ICD-10 Diagnosis

C7A.00-C7A.8	Malignant neuroendocrine tumors (carcinoid tumors)
C7B.00-C7B.8	Secondary neuroendocrine tumors
D3A.010-D3A.8	Benign neuroendocrine tumors
D13.7	Benign neoplasm of endocrine pancreas
D37.9	Neoplasm of uncertain behavior of digestive organ, unspecified
E16.8	Other specified disorders of pancreatic internal secretion
E22.0	Acromegaly and pituitary gigantism
E34.0	Carcinoid syndrome
J84.841	Neuroendocrine cell hyperplasia of infancy

Document History

Reviewed: 09/11/2023
Document History:

- 09/11/2023 – Annual Review: Wording and formatting changes. Coding Reviewed: No changes.
- 08/18/2023 – Annual Review: No Change. Coding Reviewed: No changes.
- 08/19/2022 – Annual Review: Added confirmation of diagnosis requirement by board-certified endocrinologist, add DIPNECH, insulinoma, glucagonoma, VIPoma. Coding Reviewed: Added ICD-10-CM D13.7, D37.9, E16.8, J84.841. Effective 10/1/2022 Added HCPCS J1932.
- 05/20/2022 – Select review: No changes. Coding Reviewed: No changes.
- 05/21/2021 – Annual review. Update clinical criteria to define specific Neuroendocrine tumors defined in NCCN. Coding Reviewed: No changes.
- 05/15/2020 – Annual review. No changes.Coding Review: No changes
- 08/20/2019 – Select Review. No changes. Coding reviewed: No Changes
- 03/18/2019 – Select Review. No changes. Administrative update. Coding Reviewed: No changes.
- 11/16/2018 – Annual review. No changes. HCPCS and ICD-10 coding review: No changes.

References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. 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. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.

5. The NCCN Drugs & Biologics Compendium (NCCN Compendium™) © 2023 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically.
    a. Neuroendocrine and Adrenal Tumors V2.2022. Revised December 21, 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.