Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Lanreotide (Somatuline Depot)	MP-RX-FP-83-23	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B DRUG

Service Description

This document addresses the use of Lanreotide (Somatuline Depot) **,** a somatostatin analog approved by the Food and Drug Administration (FDA) for the treatment of acromegalia and gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression free survival and carcinoid syndrome to reduce the frequency of short-acting somastatin analog rescue therapy.

Background Information

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.

Approved Indications

A. The long-term treatment of acromegalic patients who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy
B. The treatment of adult patients with unresectable, well- or moderately- differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival

Other Uses

A. Gastroenteropancreatic
B. Neuroendocrine tumors,
C. Carcinoid syndrome

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Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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

ICD-10	Description
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

Medical Necessity Guidelines

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.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Lanreotide (Somatuline Depot)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

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 (such as 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)

B. Criteria for Continuation of Therapy

i. MMM considers continuation of Somatuline Depot therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when all approval criteria are met.

a. Acromegaly: Documentation is provided that individual's IGF-1 level has decreased or normalized since initiation of therapy.

b. Carcinoid syndrome, Neuroendocrine tumors, pheochromocytoma/ paraganglioma: Documentation is provided confirming that the individual is experiencing clinical benefit from therapy as evidenced by improvement or stabilization in clinical signs and symptoms since starting therapy.

C. Authorization Duration

i. Initial Approval Duration: 1 year

ii. Reauthorization Approval Duration: 1 year

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

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

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Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Recommended Dosing Schedule
Lanreotide (Somatuline Depot) 60 mg/0.2 mL, 90 mg/0.3 mL, and 120 mg/0.5 mL single-dose prefilled syringes	• Acromegaly: 90 mg every 4 weeks for 3 months. Dose is then adjusted based on GH and/or IGF-1 levels. • GEP-NETs: 120 mg every 4 weeks (maximum of one-120 mg/0.5 mL every 28 days) • Carcinoid Syndrome: 120 mg every 4 weeks (maximum of one-120 mg/0.5 mL every 28 days)
Exceptions	
None	

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Reference Information

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™) © 2024 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically.
   a. Neuroendocrine and Adrenal Tumors V2.2024. Revised August 1, 2024.

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.

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review 08/05/2024	Added Criteria for Continuation of Therapy, authorization duration, and conditions not covered; Added dose and quantity limits; Added the following statement to the criteria for initial approval section; Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria; wording and formatting changes; coding reviewed: No changes	3/14/2025	4/2/2025
Policy Inception 08/18/2023	Elevance Health's Medical Policy adoption.	N/A	11/30/2023