# 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 drug approved by the Food and Drug Administration (FDA) 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.

**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 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 Approval**

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);

iv. Individual has a diagnosis of unresectable, well-or moderately-differentiated, locally advanced or metastatic Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs) (Label, NCCN 2A)

v. Individual has a diagnosis of carcinoid syndrome.

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. Authorization Duration**

i. Initial Approval Duration: 1 year

ii. Reauthorization Approval Duration: 1 year

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## Limits or Restrictions

## 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™) © 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.



## Policy History

| Revision Type | Summary of Changes | P&T Approval Date | MPCC Approval Date |
|---|---|---|---|
| Policy Inception | Elevance Health's Medical Policy adoption. | N/A | 11/30/2023 |

Revised: 08/18/2023