

**Lanreotide (somatuline depot)**  
**Effective 01/01/2026**

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Medical Benefit</b> <b>Pharmacy Benefit</b>	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
<b>Exceptions</b>	N/A		

### Overview

#### FDA-Approved Indications

1. Somatuline Depot
  - a. Long-term treatment of acromegalic patients who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy.
  - b. Treatment of adult patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival.
  - c. Treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.
2. Lanreotide Injection
  - a. Long-term treatment of acromegalic patients who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy.
  - b. Treatment of adult patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival.

#### Compendial Uses

1. Neuroendocrine tumors (NETs):
  - a. Tumors of the gastrointestinal (GI) tract, lung, and thymus (carcinoid tumors)
  - b. Tumors of the pancreas (islet cell tumors)
  - c. Well-differentiated grade 3 NETs with favorable biology
2. Pheochromocytoma and paraganglioma
3. Zollinger-Ellison syndrome

All other indications are considered experimental/investigational and not medically necessary.

### Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

**OR**

### **Acromegaly**

Authorization may be granted when the following criteria is met:

1. Submission of laboratory report indicating member has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range.
2. Submission of chart notes indicating member has an inadequate or partial response to surgery or radiotherapy OR a clinical reason for not having surgery or radiotherapy.

### **Zollinger-Ellison Syndrome**

Authorization may be granted when the following criteria is met:

1. Member has a diagnosis of Zollinger-Ellison syndrome.

All oncology criteria will be reviewed against Oncology Medication Review - NCCN guidelines with a Category of Evidence and Consensus of 1, 2A, or 2B.

### **Continuation of Therapy**

#### **Acromegaly**

Reauthorization may be granted for the continuation of therapy for acromegaly when there is submission of laboratory reports indicating normal current IGF-1 levels or chart notes indicating that the member's IGF-1 level has decreased or normalized since initiation of therapy.

#### **Zollinger-Ellison Syndrome**

Reauthorization may be granted for continued treatment in members requesting reauthorization when the member is experiencing clinical benefit as evidenced by improvement or stabilization in clinical signs and symptoms since starting therapy.

### **Limitations**

1. Initial approvals and reauthorizations will be granted for 12 months.

### **References**

1. American Association of Clinical Endocrinologists Acromegaly Guidelines Task Force. Medical guidelines for clinical practice for the diagnosis and treatment of acromegaly – 2011 update. *Endocr Pract.* 2011;17(suppl 4):1-44.
2. Caplin ME, Pavel M, Cwikla JB, et al. Lanreotide in metastatic enteropancreatic neuroendocrine tumors. *N Engl J Med.* 2014;371:224-233.
3. Katznelson L, Laws ER, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab.* 2014;99:3933-3951.
4. Lanreotide Injection [package insert]. Warren, NJ: Cipla USA, Inc.; December 2021.
5. Somatuline Depot [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; June 2019.

### **Review History**

12/13/2023: Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024

10/08/2025 – Reviewed and updated at October P&T. Updated policy to indicate it no longer applies to the medical benefit. Effective 01/01/2026.



