

Lanreotide (somatuline depot)
Effective 01/01/2024

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Exceptions	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	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 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. Somatuline Depot [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; June 2019.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed November 8, 2022.
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. 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.



5. The NCCN Clinical Practice Guidelines in Oncology[®] Neuroendocrine and Adrenal Tumors (Version 1.2022). © 2022 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed November 8, 2022.
6. Caplin ME, Pavel M, Cwikla JB, et al. Lanreotide in metastatic enteropancreatic neuroendocrine tumors. *N Engl J Med*. 2014;371:224-233.
7. Lanreotide Injection [package insert]. Warren, NJ: Cipla USA, Inc.; December 2021.

Review History

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

