

Octreotide acetate injection
Effective 07/01/2026

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 type="checkbox"/> Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Medical Benefit	Phone: 833-895-2611	Fax: 888-656-6671
	Pharmacy Benefit	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview

Octreotide acetate exerts pharmacologic actions similar to the natural hormone, somatostatin. It is an even more potent inhibitor of growth hormone, glucagon, and insulin than somatostatin. It also suppresses LH response to GnRH, decreases splanchnic blood flow, and inhibits release of serotonin, gastrin, vasoactive intestinal peptide, secretin, motilin, and pancreatic polypeptide.

Coverage Guidelines

If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted when all of the following diagnosis-specific criteria are met:

Acromegaly

1. Diagnosis of acromegaly
2. Submission of laboratory report indicating member has a high pretreatment IGF-1 level for age and/or gender based on the laboratory reference range.
3. Submission of chart notes indicating ONE of the following:
 - a. Member had an inadequate or partial response to surgery or radiotherapy
 - b. Clinical reason why the member has not had surgery or radiotherapy.

Neuroendocrine tumors (NETs)

1. Requested medication is being used for treatment of one of the following:
 - a. Locoregional advanced or metastatic NETs of the GI tract or unresected primary gastrinoma
 - b. Unresectable or metastatic NETs of the thymus
 - c. Unresectable or metastatic NETs of the lung
 - d. NETs of the pancreas

Carcinoid syndrome

1. Diagnosis of carcinoid syndrome

2. ONE of the following:
 - a. Requested medication will be used as monotherapy
 - b. Requested medication will be used in combination with telotristat for persistent diarrhea due to poorly controlled carcinoid syndrome
 - c. Requested medication will be used in combination with other systemic therapy options for persistent symptoms such as flushing or diarrhea, or for progressive disease

Vasoactive intestinal peptide tumors (VIPomas)

1. Requested medication will be used for management of symptoms related to hormone hypersecretion of VIPomas.

Meningiomas

1. Requested medication will be used for treatment of unresectable recurrent or progressive meningioma.

Pheochromocytoma and paraganglioma

1. Requested medication will be used for treatment of locally unresectable or metastatic pheochromocytoma and paraganglioma.

Thymomas and thymic carcinomas

1. Diagnosis of one of the following:
 - a. Thymomas
 - b. Thymic carcinomas
2. Requested medication will be used as a second-line therapy with or without prednisone
3. ONE of the following:
 - a. Unresectable disease following first-line chemotherapy for potentially resectable locally advanced disease, solitary metastasis, or ipsilateral pleural metastasis
 - b. Extrathoracic metastatic disease

Congenital hyperinsulinism (CHI)/persistent hyperinsulinemic hypoglycemia of infancy

1. Diagnosis of congenital hyperinsulinism (CHI) and persistent hyperinsulinemic hypoglycemia
2. Member is less than or equal to 1 year of age

AIDS-associated diarrhea

1. Diagnosis of AIDS-associated severe secretory diarrhea
2. Anti-microbial (e.g., ciprofloxacin or metronidazole) or anti-motility agents (e.g., loperamide or diphenoxylate and atropine) have become ineffective.

Bowel obstruction in terminal cancer

1. Diagnosis of inoperable bowel obstruction in terminal cancer
2. Requested medication is being used for management of GI symptoms

Chemotherapy- and radiation-induced diarrhea

1. Member is receiving treatment with chemotherapy or radiation
2. Member has grade 3 or greater diarrhea according to National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE)

Enterocutaneous fistula

1. Requested medication will be used for management of volume depletion for enterocutaneous fistula



Gastroesophageal varices

- 1. Requested medication will be used for treatment of acute bleeding of gastroesophageal varices associated with cirrhosis.

Islet cell tumors

- 1. Requested medication will be used stabilization of blood glucose levels in patients with functioning islet cell tumors (e.g., insulinomas or glucagonomas).

Pancreatic fistulas

- 1. Requested medication will be used for prevention or treatment of pancreatic fistulas following pancreatic surgery.

Pituitary adenoma

- 1. Diagnosis of pituitary adenoma.

Short bowel syndrome

- 1. Requested medication will be used for treatment of short bowel syndrome when the daily intravenous fluid requirement is greater than 3 liters.

Zollinger-Ellison syndrome

- 1. Diagnosis of Zollinger-Ellison syndrome.

Continuation of Therapy

Requests for reauthorization will be approved when the following diagnosis-specific criteria are met:

Acromegaly

- 1. Submission of laboratory reports or chart notes indicating member’s IGF-1 level has decreased or normalized since initiation of therapy.

Carcinoid syndrome, VIPomas, AIDS-associated diarrhea, bowel obstruction, chemotherapy/radiation-induced diarrhea, islet cell tumors, and Zollinger-Ellison syndrome

- 1. Member is experiencing clinical benefit as evidenced by improvement or stabilization in clinical signs and symptoms since initiation of therapy.

All other indications

- 1. All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

Limitations

- 1. Initial approvals for congenital hyperinsulinism, pancreatic fistulas or gastroesophageal varices will be granted for 6 months
- 2. Authorizations for all other diagnoses will be granted approval for 12 months
- 3. Reauthorizations will be granted for 12 months
- 4. The following quantity limits apply on the pharmacy benefit:

Drug Name	Quantity Limit
Octreotide 50mcg/mL	90 ampules per 30 days
Octreotide 100mcg/mL	90 ampules per 30 days



Octreotide 200mcg/mL	45 vials per 30 days
Octreotide 500mcg/mL	90 ampules per 30 days
octreotide 1000mcg/mL	9 vials per 30 days
octreotide 5000mcg/5 mL	9 vials per 30 days

References

1. Adachi T, Kuroki T, Kitasato A, et al. Safety and efficacy of early drain removal and triple-drug therapy to prevent pancreatic fistula after distal pancreatectomy. *Pancreatology* 2015;15:411-416.
2. Alberta Provincial CNS Tumour Team. Pituitary adenomas. Clinical Practice Guideline No. CNS-006 Edmonton, AB: Alberta Health Services, Cancer Care; August 2012.
3. Allen PJ, Gonen M, Brennan MF, et al. Pasireotide for postoperative pancreatic fistula. *N Engl J Med*. 2014;370(21):2014-2022.
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. American Gastroenterological Association. American Gastroenterological Association medical position statement: Short bowel syndrome and intestinal transplantation. *Gastroenterology*. 2003;124(4):1105-1110.
6. Bynfezia Pen [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries Ltd.; January 2020.
7. Corley DA, Cello JP, Adkisson W, et al. Octreotide for acute esophageal variceal bleeding: A meta-analysis. *Gastroenterology*. 2001;120(4):946-954.
8. Dorta G. Role of octreotide and somatostatin in the treatment of intestinal fistulae. *Digestion*. 1999;60 Suppl 2:53-56.
9. Edmunds MC, Chen JD, Soykan I, et al. Effect of octreotide on gastric and small bowel motility in patients with gastroparesis. *Aliment Pharmacol Ther*. 1998;12(2):167-174.
10. Erstad BL. Octreotide for acute variceal bleeding. *Ann Pharmacother*. 2001;35(5):618-626.
11. Freitas DS, Sofia C, Pontes JM, et al. Octreotide in acute bleeding esophageal varices: A prospective randomized study. *Hepatogastroenterology*. 2000;47(35):1310-1314.
12. Fried M. Octreotide in the treatment of refractory diarrhea. *Digestion*. 1999;60:42-46.
13. Gøtzsche PC, Hróbjartsson A. Somatostatin analogues for acute bleeding oesophageal varices. *Cochrane Database Syst Rev*. 2008;(3):CD000193.
14. Gross M, Schiemann U, Muhlhofer A, Zoller WG. Meta-analysis: Efficacy of therapeutic regimens in ongoing variceal bleeding. *Endoscopy*. 2001;33(9):737-746.
15. Gurusamy KS, Koti R, Fusai G, Davidson BR. Somatostatin analogues for pancreatic surgery. *Cochrane Database Syst Rev*. 2013;4:CD008370.
16. Harris AG, O'Dorisio TM, Woltering EA, et al. Consensus statement: Octreotide dose titration in secretory diarrhea. *Diarrhea Management Consensus Development Panel*. *Dig Dis Sci*. 1995;40(7):1464-1473.
17. Imperiale TF, Teran JC, McCullough AJ. A meta-analysis of somatostatin versus vasopressin in the management of acute esophageal variceal hemorrhage. *Gastroenterology*. 1995;109(4):1289-1294.
18. Jamil M, Ahmed U, Sobia H. Role of somatostatin analogues in the management of enterocutaneous fistulae. *J Coll Physicians Surg Pak*. 2004;14(4):237-240.
19. Katznelson L, Laws ER, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab*. 2014;99:3933-3951.
20. Leandros E, Antonakis PT, Albanopoulos K, et al. Somatostatin versus octreotide in the treatment of patients with gastrointestinal and pancreatic fistulas. *Can J Gastroenterol*. 2004;18(5):303-306.



21. Li-Ling J, Irving M. Somatostatin and octreotide in the prevention of postoperative pancreatic complications and the treatment of enterocutaneous pancreatic fistulas: A systematic review of randomized controlled trials. *Br J Surg.* 2001;88(2):190-199.
22. Loehrer PJ Sr, Wang W, Johnson DH, et al. Octreotide alone or with prednisone in patients with advanced thymoma and thymic carcinoma: An Eastern Cooperative Oncology Group Phase II Trial. *J Clin Oncol.* 2004;22(2):293-299.
23. Machado NO. Pancreatic fistula after pancreatectomy: Definitions, risk factors, preventive measures, and management – Review. *Int J Surg Oncol.* 2012;2012:602478.
24. Mercadante S, Ripamonti C, Casuccio A, et al. Comparison of octreotide and hyoscine butylbromide in controlling gastrointestinal symptoms due to malignant inoperable bowel obstruction. *Support Care Cancer.* 2000;8(3):188-191.
25. Mystakidou K, Tsilika E, Kalaidopoulou O, et al. Comparison of octreotide administration vs conservative treatment in the management of inoperable bowel obstruction in patients with far advanced cancer: A randomized, double-blind, controlled clinical trial. *Anticancer Res.* 2002;22(2B):1187-1192.
26. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: <http://www.nccn.org>. Accessed June 11, 2019.
27. Octreotide acetate [package insert]. Rockford, IL: Mylan Institutional LLC; September 2017.
28. Peeters M, Van den Brande J, Francque S. Diarrhea and the rationale to use Sandostatin. *Acta Gastroenterol Belg.* 2010;73(1):25-36.
29. Rahbour G, Siddiqui MR, Ullah MR, et al. A meta-analysis of outcomes following use of somatostatin and its analogues for the management of enterocutaneous fistulas. *Ann Surg.* 2012;256(6):946-954.
30. Rinke A, Muller H, Schade-Brittinger C, et al. Placebo-controlled, double-blind, prospective, randomized study on the effect of octreotide LAR in the control of tumor growth in patients with metastatic neuroendocrine midgut tumors: a report from the PROMID study group. *J Clin Oncol.* 2009;27:4656-4663.
31. Ripamonti C, Mercadante S, Groff L, et al. Role of octreotide, scopolamine butylbromide, and hydration in symptom control of patients with inoperable bowel obstruction and nasogastric tubes: A prospective randomized trial. *J Pain Symptom Manage.* 2000;19(1):23-34.
32. Sandostatin [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2019.
33. Sandostatin LAR Depot [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2019.

Review History

1/20/2021 – Transitioned from SGM to Custom Criteria; added Mycapssa capsules and Bynfezia pen to criteria. Effective 02/01/2021.

10/11/2023 – Reviewed and Updated at Oct P&T; defined infant for diagnosis of Congenital hyperinsulinism (CHI)/persistent hyperinsulinemic hypoglycemia of infancy. Effective 1/1/24

10/08/2025 – Reviewed and updated at October P&T. Added language for members who are new to the plan. Removed Bynfezia from the policy due to product discontinuation. Updated policy to indicate it no longer applies to the medical benefit. Effective 01/01/2026.

02/11/2026 – Reviewed at February P&T. Updated criteria for acromegaly to require submission of medical records to demonstrate initial and reauthorization criteria have been met. Effective 05/01/2026.

04/15/2026 – Reviewed and updated at April P&T. Removed Mycapssa, Sandostatin LAR and octreotide 10 mg, 20 mg and 30 mg kit from policy as agents are moving to nonformulary status. Effective 07/01/2026.

