Mass General Brigham
Health Plan

# Sandostatin (octreotide acetate injection)
# Sandostatin LAR Depot (octreotide acetate for injectable suspension)
# Mycapssa (octreotide acetate oral capsule)
# octreotide acetate injection
# Bynfezia Pen (octreotide acetate injection)
# Effective 02/01/2021

| | | | |
|---|---|---|---|
| **Plan** | ☐ MassHealth UPPL<br>☒Commercial/Exchange | **Program Type** | ☒ Prior Authorization<br>☒ Quantity Limit<br>☐ Step Therapy |
| **Benefit** | ☒ Pharmacy Benefit<br>☒ Medical Benefit (NLX) | | |
| **Specialty Limitations** | This medication has been designated specialty and must be filled at a contracted specialty pharmacy. | | |
| **Contact Information** | **Specialty Medications** | | |
| | All Plans | Phone: 866-814-5506 | Fax: 866-249-6155 |
| | **Non-Specialty Medications** | | |
| | MassHealth | Phone: 877-433-7643 | Fax: 866-255-7569 |
| | Commercial | Phone: 800-294-5979 | Fax: 888-836-0730 |
| | Exchange | Phone: 855-582-2022 | Fax: 855-245-2134 |
| | **Medical Specialty Medications (NLX)** | | |
| | All Plans | Phone: 844-345-2803 | Fax: 844-851-0882 |
| **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**

**Acromegaly**

Authorization of 12 months may be granted for the treatment of acromegaly when all of the following criteria are met:

1. Member has a high pretreatment IGF-1 level for age and/or gender based on the laboratory reference range.
2. Member had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason why the member has not had surgery or radiotherapy.

**Neuroendocrine tumors (NETs)**

1. Tumors of the gastrointestinal (GI) tract (carcinoid tumor)
   Authorization of 12 months may be granted for treatment of locoregional advanced or metastatic NETs of the GI tract or unresected primary gastrinoma.
2. Tumors of the thymus (carcinoid tumor)

Authorization of 12 months may be granted for treatment of unresectable or metastatic NETs of the thymus.

3. Tumors of the lung (carcinoid tumor)
   Authorization of 12 months may be granted for treatment of unresectable or metastatic NETs of the lung.
4. Tumors of the pancreas
   Authorization of 12 months may be granted for treatment of NETs of the pancreas.

**Carcinoid syndrome**
Authorization of 12 months may be granted for treatment of carcinoid syndrome when it is used in any of the following clinical settings:

1. As a single agent
2. In combination with telotristat for persistent diarrhea due to poorly controlled carcinoid syndrome
3. In combination with other systemic therapy options for persistent symptoms such as flushing or diarrhea, or for progressive disease

**Vasoactive intestinal peptide tumors (VIPomas)**
Authorization of 12 months may be granted for management of symptoms related to hormone hypersecretion of VIPomas.

**Meningiomas**
Authorization of 12 months may be granted for treatment of unresectable recurrent or progressive meningioma.

**Pheochromocytoma and paraganglioma**
Authorization of 12 months may be granted for treatment of locally unresectable or metastatic pheochromocytoma and paraganglioma.

**Thymomas and thymic carcinomas**
Authorization of 12 months may be granted for treatment of thymomas and thymic carcinomas when the requested drug is used as a second-line therapy with or without prednisone in any of the following clinical settings:

1. Unresectable disease following first-line chemotherapy for potentially resectable locally advanced disease, solitary metastasis, or ipsilateral pleural metastasis
2. Extrathoracic metastatic disease

**Congenital hyperinsulinism (CHI)/persistent hyperinsulinemic hypoglycemia of infancy (octreotide and Sandostatin only)**
Authorization of 6 months may be granted for treatment of CHI and persistent hyperinsulinemic hypoglycemia in an infant.

**AIDS-associated diarrhea**
Authorization of 12 months may be granted for treatment of AIDS-associated severe secretory diarrhea when 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**
Authorization of 12 months may be granted for management of GI symptoms (e.g., nausea, pain, vomiting) of inoperable bowel obstruction in members with terminal cancer.

**Chemotherapy- and radiation-induced diarrhea**
Authorization of 12 months may be granted for treatment of chemotherapy- or radiation-induced diarrhea when any of the following criteria are met:
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**
Authorization of 12 months may be granted for management of volume depletion from enterocutaneous fistula.

**Gastroesophageal varices**
Authorization of 6 months may be granted for treatment of acute bleeding of gastroesophageal varices associated with cirrhosis.

**Islet cell tumors**
Authorization of 12 months may be granted for stabilization of blood glucose levels in patients with functioning islet cell tumors (e.g., insulinomas or glucagonomas).

**Pancreatic fistulas**
Authorization of 6 months may be granted for prevention and treatment of pancreatic fistulas following pancreatic surgery.

**Pituitary adenoma**
Authorization of 12 months may be granted for treatment of pituitary adenoma.

**Short bowel syndrome**
Authorization of 12 months may be grated for treatment of short bowel syndrome when the daily intravenous fluid requirement is greater than 3 liters.

**Zollinger-Ellison syndrome**
Authorization of 12 months may be grated for treatment of Zollinger-Ellison syndrome.

**<u>Continuation of Therapy</u>**
**Acromegaly**
Authorization of 12 months may be granted for continuation of therapy for acromegaly when the 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**
Authorization of 12 months 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 initiation of therapy.

**All other indications**
All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

**Limitations**

1. Initial approvals for congenital hyperinsulinism 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:

| | |
|---|---|
| Mycapssa 20mg | 120 capsules per 30 days |
| Bynfezia Pen 2500mcg/mL (2.8mL) | 7 pens per 30 days |
| Standostatin LAR Depot 10mg & 30mg | 1 kit per 28 days |
| Standostatin LAR Depot 20mg | 2 kits per 28 days |
| Sandostatin or Octreotide 50mcg/mL | 90 ampules per 30 days |
| Sandostatin or Octreotide 100mcg/mL | 90 ampules per 30 days |
| Sandostatin or Octreotide 200mcg/mL | 45 vials per 30 days |
| Sandostatin or Octreotide 500mcg/mL | 90 ampules per 30 days |
| Standostatin or octreotide 1000mcg/mL | 9 vials per 30 days |
| Standostatin or octreotide 5000mcg/5 mL | 9 vials per 30 days |

**References**


1. Octreotide acetate [package insert]. Rockford, IL: Mylan Institutional LLC; September 2017.
2. Sandostatin [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2019.
3. Sandostatin LAR Depot [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2019.
4. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org. Accessed June 11, 2019.
5. Katznelson L, Laws ER, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2014;99:3933-3951.
6. 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.
7. The NCCN Clinical Practice Guidelines in Oncology® Neuroendocrine Tumors (Version 1.2019). © 2019 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed June 11, 2019.
8. 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.
9. The NCCN Clinical Practice Guidelines in Oncology® Central Nervous System Cancers (Version 2.2018). © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed January 26, 2019.
10. The NCCN Clinical Practice Guidelines in Oncology® Thymomas and Thymic Carcinomas. (Version 2.2018). © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed January 26, 2019.
11. The NCCN Clinical Practice Guidelines in Oncology® Palliative Care (Version 2.2019). © 2019 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed June 11, 2019.
12. 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.
13. Fried M. Octreotide in the treatment of refractory diarrhea. Digestion. 1999,60:42-46.
14. 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.
15. 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.

16. 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.
17. Dorta G. Role of octreotide and somatostatin in the treatment of intestinal fistulae. Digestion. 1999;60 Suppl 2:53-56.
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. 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.
20. Freitas DS, Sofia C, Pontes JM, et al. Octreotide in acute bleeding esophageal varices: A prospective randomized study. Hepatogastroenterology. 2000;47(35):1310-1314.
21. 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.
22. Gøtzsche PC, Hróbjartsson A. Somatostatin analogues for acute bleeding oesophageal varices. Cochrane Database Syst Rev. 2008;(3):CD000193.
23. Erstad BL. Octreotide for acute variceal bleeding. Ann Pharmacother. 2001;35(5):618-626.
24. Corley DA, Cello JP, Adkisson W, et al. Octreotide for acute esophageal variceal bleeding: A meta-analysis. Gastroenterology. 2001;120(4):946-954.
25. Gross M, Schiemann U, Muhlhofer A, Zoller WG. Meta-analysis: Efficacy of therapeutic regimens in ongoing variceal bleeding. Endoscopy. 2001;33(9):737-746.
26. 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.
27. Machado NO. Pancreatic fistula after pancreatectomy: Definitions, risk factors, preventive measures, and management – Review. Int J Surg Oncol. 2012;2012:602478.
28. 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.
29. Gurusamy KS, Koti R, Fusai G, Davidson BR. Somatostatin analogues for pancreatic surgery. Cochrane Database Syst Rev. 2013;4:CD008370.
30. Alberta Provincial CNS Tumour Team. Pituitary adenomas. Clinical Practice Guideline No. CNS-006 Edmonton, AB: Alberta Health Services, Cancer Care; August 2012.
31. Peeters M, Van den Brande J, Francque S. Diarrhea and the rationale to use Sandostatin. Acta Gastroenterol Belg. 2010;73(1):25-36.
32. 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.
33. American Gastroenterological Association. American Gastroenterological Association medical position statement: Short bowel syndrome and intestinal transplantation. Gastroenterology. 2003;124(4):1105-1110.
34. 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.
35. 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.
36. Allen PJ, Gonen M, Brennan MF, et al. Pasireotide for postoperative pancreatic fistula. N Engl J Med. 2014;370(21):2014-2022.
37. Bynfezia Pen [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries Ltd.; January 2020.
38. Mycapssa [package insert]. Needham, MA: Chiasma, Inc.; June 2020.

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