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
Effective 05/01/2026

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 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 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 (octreotide and Sandostatin only)

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.

<u>Continuation of Therapy</u>

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
Mycapssa 20mg	120 capsules per 30 days
Sandostatin 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
Sandostatin or octreotide 1000mcg/mL	9 vials per 30 days
Sandostatin or octreotide 5000mcg/5 mL	9 vials per 30 days

References

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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.