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 01/01/2026

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

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 (up to age 1).

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, 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

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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.