

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 | <input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange | Program Type | <input checked="" type="checkbox"/> Prior Authorization |
| Benefit | <input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX) | | <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy |
| 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 | Mycapssa is only available through the pharmacy benefit. | | |

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 granted 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 granted for treatment of Zollinger-Ellison syndrome.

Continuation of Therapy

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

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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:

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|---|--------------------------|
| 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 |

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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.

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