AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Octreotide Products	Page:	1 of 8
Effective Date:	4/29/2025	Last Review Date:	4/8/2025
Applies to:	☒Florida Kids ☒Pennsylvania Kids	☒New Jersey ☒Virginia	☒Maryland ☒Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for octreotide products under the patient's prescription drug benefit.

Description:

FDA-approved Indications

- octreotide acetate injection:
  - Indicated to reduce blood levels of growth hormone (GH) and insulin growth factor-1 (IGF-1; somatomedin C) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses.
  - Indicated for the symptomatic treatment of patients with metastatic carcinoid tumors where it suppresses or inhibits the severe diarrhea and flushing episodes associated with the disease.
  - Indicated for the treatment of the profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors.
- octreotide acetate for injectable suspension : octreotide acetate for injectable suspension is indicated in patients who have responded to and tolerated octreotide acetate injection for:
  - Long-term maintenance therapy in acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. The goal of treatment in acromegaly is to reduce GH and IGF-1 levels to normal.
  - Long-term treatment of the severe diarrhea and flushing episodes associated with metastatic carcinoid tumors.
  - Long-term treatment of the profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors.

Limitations of Use:
In patients with carcinoid syndrome and VIPomas, the effect of octreotide acetate injection and octreotide acetate for injectable suspension on tumor size, rate of growth and development of metastases, has not been determined.

- Mycapssa is indicated for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide.

Compendial Uses (applies to injectable products)

- Neuroendocrine tumors (NETs)
  - Tumors of the gastrointestinal (GI) tract, lung, and thymus (carcinoid tumors)
  - Tumors of the pancreas (islet cell tumors)
  - Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)
- Pheochromocytoma and paraganglioma
- Thymomas and thymic carcinomas
- Congenital hyperinsulinism (CHI)/persistent hyperinsulinemic hypoglycemia of infancy (PHHI)(octreotide only)
- Acquired immune deficiency syndrome (AIDS)-associated diarrhea
- Inoperable bowel obstruction
- Cancer-related diarrhea
- Enterocutaneous fistula
- Gastroesophageal varices
- Pancreatic fistulas
- Pituitary adenoma
- Short bowel syndrome
- Zollinger-Ellison syndrome
- Meningiomas

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Mycapssa (octreotide delayed-release capsule)
Octreotide acetate for injectable suspension
Octreotide acetate injection

Policy/Guideline:

Documentation:

Submission of the following information is necessary to initiate the prior authorization review:

- Acromegaly:
  - For initial approval: Laboratory report indicating high pretreatment insulin-like growth factor-1 (IGF-1) level and chart notes indicating an inadequate or partial

response to surgery or radiotherapy or a clinical reason for not having surgery or radiotherapy.
    - For continuation: Laboratory report indicating normal current IGF-1 levels or chart notes indicating that the member's IGF-1 level has decreased or normalized since initiation of therapy.
- Cancer-related diarrhea: Chart notes indicating grade 3 or 4 diarrhea.

Coverage Criteria:

Note: All requests require that the member is unable to take octreotide acetate injection followed by octreotide acetate for injectable suspension for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

Acromegaly
Authorization of 12 months may be granted for the treatment of acromegaly when ALL the following criteria are met:
- Member has a high pretreatment IGF-1 level for age and/or gender based on the laboratory reference range.
- 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.
- For Mycapssa requests, member has previously responded to and tolerated treatment with octreotide or lanreotide

Neuroendocrine Tumors (NETs) (injectable products only)
- Authorization of 12 months may be granted for treatment of NETs of the gastrointestinal (GI) tract, lung, and thymus (carcinoid tumors).
- Authorization of 12 months may be granted for treatment of NETs of the pancreas (islet cell tumors), including gastrinomas, glucagonomas, and insulinomas.
- Authorization of 12 months may be granted for treatment of gastroenteropancreatic neuroendocrine tumors (GEP-NETs).

Carcinoid Syndrome (injectable products only)
Authorization of 12 months may be granted for treatment of carcinoid syndrome.

Vasoactive Intestinal Peptide Tumors (VIPomas) (injectable products only)
Authorization of 12 months may be granted for management of symptoms related to hormone hypersecretion of VIPomas.

Pheochromocytoma and Paraganglioma (injectable products only)
Authorization of 12 months may be granted for treatment of pheochromocytoma and paraganglioma.

Thymomas and Thymic Carcinomas (injectable products only)
Authorization of 12 months may be granted for treatment of thymomas and thymic carcinomas.

Congenital Hyperinsulinism (CHI)/Persistent Hyperinsulinemic Hypoglycemia of Infancy (octreotide only)
Authorization of 6 months may be granted for treatment of CHI and persistent hyperinsulinemic hypoglycemia in an infant.

AIDS-Associated Diarrhea (injectable products only)
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.

Inoperable Bowel Obstruction in Cancer (injectable products only)
Authorization of 12 months may be granted for management of GI symptoms (e.g., nausea, pain, vomiting) of inoperable bowel obstruction in members with cancer.

Cancer-Related Diarrhea (injectable products only)
Authorization of 12 months may be granted for treatment of cancer-related diarrhea when the member has grade 3 or greater diarrhea according to National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE).

Enterocutaneous Fistula (injectable products only)
Authorization of 12 months may be granted for management of volume depletion from enterocutaneous fistula.

Gastroesophageal Varices (injectable products only)
Authorization of 6 months may be granted for treatment of acute bleeding of gastroesophageal varices associated with cirrhosis.

Pancreatic Fistulas (injectable products only)
Authorization of 6 months may be granted for prevention and treatment of pancreatic fistulas following pancreatic surgery.

Pituitary Adenoma (injectable products only)
Authorization of 12 months may be granted for treatment of pituitary adenoma.

Short Bowel Syndrome (injectable products only)
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 (injectable products only)
Authorization of 12 months may be grated for treatment of Zollinger-Ellison syndrome.

Meningiomas (injectable products only)
Authorization of 12 months may be granted for treatment of meningiomas when used in combination with everolimus for surgically inaccessible recurrent or progressive disease.

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.

NETs, Carcinoid Syndrome, Vipomas, Pheochromocytoma/Paraganglioma, Thymomas/Thymic Carcinomas, AIDS-Associated Diarrhea, Bowel Obstruction, Cancer-Related Diarrhea, Zollinger-Ellison Syndrome, and Meningiomas (injectable products only)
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 requirements in the coverage criteria.

Approval Duration and Quantity Restrictions:

Approval:
Pancreatic fistulas, Gastroesophageal varices, Congenital hyperinsulinism (CHI)/persistent hyperinsulinemic hypoglycemia of infancy: Initial and Renewal - 6 months

All other indications: Initial and Renewal - 12 months

Quantity Level Limits:

- Octreotide Inj 50 mcg/mL single dose ampules, syringes, vials: 90 ampules/ syringes / vials per 30 days
- Octreotide Inj 100 mcg/mL single dose ampules, syringes, vials: 90 ampules/ syringes / vials per 30 days
- Octreotide Inj 500 mcg/mL single dose ampules, syringes, vials: 90 ampules / syringes / vials per 30 days
- Octreotide Inj 200 mcg/mL (5 mL multi-dose vials): 45 vials (45,000 units) per 30 days
- Octreotide Inj 1000 mcg/mL (5 mL multi-dose vials): 9 vials (45,000 units) per 30 days
- Mycapssa (octreotide acetate) DR capsules 20 mg: 112 capsules per 28 days
- Octreotide acetate for inj susp 10 mg single-dose kit: 10 mg (1 kit) per 28 days
- Octreotide acetate for inj susp 20 mg single-dose kit: 40 mg (2 kits) per 28 days
- Octreotide acetate for inj susp 30 mg single-dose kit: 30 mg (1 kit) per 28 days

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