



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Octreotide Products

Page: 1 of 9

Effective Date: 4/1/2024

Last Review Date: 3/2024

Applies to:	<input checked="" type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input type="checkbox"/> Florida Kids
	<input type="checkbox"/> New Jersey	<input type="checkbox"/> Maryland	<input type="checkbox"/> Michigan
	<input type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Virginia	<input type="checkbox"/> Arizona

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:

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. octreotide acetate/Sandostatin:
 - a. 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.
 - b. 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.
 - c. Indicated for the treatment of the profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors.

2. Sandostatin LAR: Sandostatin LAR Depot is indicated in patients who have responded to and tolerated Sandostatin subcutaneous injection for:
 - a. 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.
 - b. Long-term treatment of the severe diarrhea and flushing episodes associated with metastatic carcinoid tumors.
 - c. Long-term treatment of the profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors.



AETNA BETTER HEALTH®
Coverage Policy/Guideline

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Page: 2 of 9

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

B. Compendial Uses (applies to injectable products)

1. Neuroendocrine tumors (NETs):
 - a. Tumors of the gastrointestinal (GI) tract, lung, and thymus (carcinoid tumors)
 - b. Tumors of the pancreas (islet cell tumors)
 - c. Well-differentiated grade 3 NETs with favorable biology
 - d. Gastroenteropancreatic NETs
2. Pheochromocytoma and paraganglioma
3. Thymomas and thymic carcinomas
4. Congenital hyperinsulinism (CHI)/persistent hyperinsulinemic hypoglycemia of infancy (PHHI) (octreotide and Sandostatin only)
5. Acquired immune deficiency syndrome (AIDS)-associated diarrhea
6. Inoperable bowel obstruction
7. Cancer-related diarrhea
8. Enterocutaneous fistula
9. Gastroesophageal varices
10. Pancreatic fistulas
11. Pituitary adenoma
12. Short bowel syndrome
13. Zollinger-Ellison syndrome

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

Applicable Drug List:

Octreotide Acetate injection
Sandostatin LAR Depot (octreotide acetate for injectable suspension)
Mycapssa (octreotide delayed-release capsule)
Sandostatin (octreotide acetate injection)

Policy/Guideline:

Documentation:



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Octreotide Products

Page: 3 of 9

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Last Review Date: 3/2024

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

A. For acromegaly:

1. 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.
2. 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.

B. Cancer-related diarrhea: Chart notes indicating grade 3 or 4 diarrhea.

Criteria for Initial Approval:

A. 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.
3. For Mycapssa requests, member has previously responded to and tolerated treatment with octreotide or lanreotide.

B. Neuroendocrine tumors (NETs) (injectable products only)

1. Tumors of the gastrointestinal (GI) tract (carcinoid tumor)
Authorization of 12 months may be granted for treatment of NETs of the GI tract.
2. Tumors of the thymus (carcinoid tumor)
Authorization of 12 months may be granted for treatment of NETs of the thymus.
3. Tumors of the lung (carcinoid tumor)
Authorization of 12 months may be granted for treatment of NETs of the lung.
4. Tumors of the pancreas (islet cell tumors)
Authorization of 12 months may be granted for treatment of NETs of the pancreas, including gastrinomas, glucagonomas, and insulinomas.



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Octreotide Products

Page: 4 of 9

Effective Date: 4/1/2024

Last Review Date: 3/2024

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- Well-differentiated grade 3 NETs with favorable biology
Authorization of 12 months may be granted for treatment of well-differentiated grade 3 NETs with favorable biology (e.g., relatively low Ki-67 [less than 55%], somatostatin receptor [SSR] positive imaging).
- Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)
Authorization of 12 months may be granted for treatment of GEP-NETs.

C. Carcinoid syndrome (injectable products only)

Authorization of 12 months may be granted for treatment of carcinoid syndrome.

D. 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.

E. Pheochromocytoma and paraganglioma (injectable products only)

Authorization of 12 months may be granted for treatment of pheochromocytoma and paraganglioma.

F. Thymomas and thymic carcinomas (injectable products only)

Authorization of 12 months may be granted for treatment of thymomas and thymic carcinomas.

G. 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.

H. 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.



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Octreotide Products

Page: 5 of 9

Effective Date: 4/1/2024

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	<input type="checkbox"/> New Jersey	<input type="checkbox"/> Maryland	<input type="checkbox"/> Michigan
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I. 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.

J. 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).

K. Enterocutaneous fistula (injectable products only)

Authorization of 12 months may be granted for management of volume depletion from enterocutaneous fistula.

L. Gastroesophageal varices (injectable products only)

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

M. Pancreatic fistulas (injectable products only)

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

N. Pituitary adenoma (injectable products only)

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

O. Short bowel syndrome (injectable products only)

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

P. Zollinger-Ellison syndrome (injectable products only)

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



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Octreotide Products

Page: 6 of 9

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Last Review Date: 3/2024

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	<input type="checkbox"/> New Jersey	<input type="checkbox"/> Maryland	<input type="checkbox"/> Michigan
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Continuation of Therapy:

A. 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.

B. NETs, Carcinoid syndrome, VIPomas, pheochromocytoma/paraganglioma, thymomas/thymic carcinomas, AIDS-associated diarrhea, bowel obstruction, cancer-related diarrhea, and Zollinger-Ellison syndrome (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.

C. All other indications

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization 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 Limit:

Medication	Standard Limit
Sandostatin (octreotide) Inj 50 mcg/mL	90 ampules per 30 days
Sandostatin (octreotide) Inj 100 mcg/mL	90 ampules per 30 days
Sandostatin (octreotide) Inj 500 mcg/mL	90 ampules per 30 days
Octreotide Inj 50 mcg/mL single dose ampules, syringes, vials	90 ampules/syringes/vials per 30 days



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Octreotide Products Page: 7 of 9

Effective Date: 4/1/2024 Last Review Date: 3/2024

Applies to: Illinois Florida Florida Kids
 New Jersey Maryland Michigan
 Pennsylvania Kids Virginia Arizona

Medication	Standard Limit
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) delayed-release capsules 20 mg	112 capsules per 28 days
Sandostatin (octreotide) Kit LAR 10 mg	10 mg (1 Kit) per 28 days
Sandostatin (octreotide) Kit LAR 20 mg	40 mg (2 Kits) per 28 days
Sandostatin (octreotide) Kit LAR 30 mg	30 mg (1 Kit) per 28 days

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AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Octreotide Products Page: 8 of 9

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AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Octreotide Products Page: 9 of 9

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