Reference number(s)
1734-A

Specialty Guideline Management octreotide products

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Sandostatin	octreotide acetate injection
Bynfezia Pen	octreotide acetate injection
Sandostatin LAR Depot	octreotide acetate for injectable suspension
Mycapssa	octreotide delayed-release capsule

Indications

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.

FDA-Approved Indications[1-6]

Sandostatin, Bynfezia Pen, 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 treatment of severe diarrhea and flushing episodes associated with metastatic carcinoid tumors
- Indicated for the treatment of the profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (VIPomas)

Limitations of Use

Improvement in clinical signs and symptoms, or reduction in tumor size or rate of growth, were not shown in clinical trials performed with Sandostatin Injection; these trials were not optimally designed to detect such effects.

Sandostatin LAR Depot, octreotide acetate for injectable suspension

- Indicated in patients in whom initial treatment with Sandostatin Injection/octreotide acetate injection has been shown to be effective and tolerated 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 (VIPomas).

Limitations of Use

In patients with carcinoid syndrome and VIPomas, the effect of Sandostatin Injection and Sandostatin LAR Depot on tumor size, rate of growth and development of metastases, has not been determined.

Mycapssa

- 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 and adrenal tumors (NETs)[9-11]
  - 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[9]
- Meningiomas[9]
- Merkel cell carcinoma[9]
- Cancer-related diarrhea[12]
- Inoperable malignant bowel obstruction[12]
- Acquired immune deficiency syndrome (AIDS)-associated diarrhea[13]
- Enterocutaneous fistula[10]
- Pancreatic fistulas[10]
- Gastroesophageal varices[10]
- Pituitary adenoma[14]
- Short bowel syndrome[15,16]

- Zollinger-Ellison syndrome[11]
- Congenital hyperinsulinism (CHI)/persistent hyperinsulinemic hypoglycemia of infancy (PHHI)(octreotide and Sandostatin only)

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

Documentation

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

- For 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 that surgery or radiotherapy are not an option.
  - 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.
- For cancer-related diarrhea: Chart notes indicating grade 3 or 4 diarrhea.

Coverage Criteria

Acromegaly[1-8]

Authorization of 12 months may be granted for the treatment of acromegaly when all of 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 meets one of the following:
  - Member had an inadequate or partial response to surgery or radiotherapy.
  - Surgery or radiotherapy are not an option for the member.
- For Mycapssa requests, member has previously responded to and tolerated treatment with octreotide or lanreotide.

Neuroendocrine Tumors (NETs) (injectable products only)[1-5,9,11]

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).

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

Carcinoid Syndrome (injectable products only)[1-5,9,11]

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

Vasoactive Intestinal Peptide Tumors (VIPomas) (injectable products only)[1-5,11]

Authorization of 12 months may be granted for management of symptoms related to hormone hypersecretion of VIPomas.

Thymomas (injectable products only)[9]

Authorization of 12 months may be granted for treatment of thymomas.

Meningiomas (injectable products only)[9]

Authorization of 12 months may be granted for treatment of meningiomas when used in combination with everolimus for surgically inaccessible recurrent or progressive disease.

Merkel Cell Carcinoma (LAR injectable products only)[9]

Authorization of 12 months may be granted for treatment of somatostatin receptor-positive Merkel cell carcinoma as a single agent when the member has a contraindication to anti-PD-L1 and anti-PD-1 therapy and one of the following criteria is met:

- The member has regional disease.
- The member has disease progression while on anti-PD-L1 or anti-PD-1 therapy.

Cancer-Related Diarrhea (injectable products only)[12]

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

Inoperable Malignant Bowel Obstruction (injectable products only)[12]

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.

AIDS-Associated Diarrhea (injectable products only)[15]

Authorization of 12 months may be granted for treatment of AIDS-associated severe secretory diarrhea when antimicrobial (e.g., ciprofloxacin or metronidazole) or antimotility agents (e.g., loperamide or diphenoxylate and atropine) have become ineffective.

Enterocutaneous Fistula (injectable products only)[10]

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

Pancreatic Fistulas (injectable products only)[10,17]

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

Gastroesophageal Varices (injectable products only)[10]

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

Pituitary Adenoma (injectable products only)[14]

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

Short Bowel Syndrome (injectable products only)[15,16]

Authorization of 12 months may be granted for treatment of short bowel syndrome in members with large volume stool losses when fluid and electrolyte management is problematic.

Zollinger-Ellison Syndrome (injectable products only)[11]

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

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.

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, Thymomas, Meningiomas, Merkel Cell Carcinoma, Cancer-Related Diarrhea, Inoperable Malignant Bowel Obstruction, AIDS-Associated 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.

All Other Indications

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

References

1. Sandostatin [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2024.
2. Bynfezia Pen [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries Inc.; February 2025.
3. Octreotide acetate [package insert]. Morgantown, WV: Mylan Institutional LLC; July 2024.
4. Sandostatin LAR Depot [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2024.
5. Octreotide acetate for injectable suspension. Parsippany, NJ: Teva Pharmaceuticals; July 2024.
6. Mycapssa [package insert]. Scotland, UK: MW Encap Ltd.; August 2024.
7. Katznelson L, Laws ER, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2014;99:3933-3951.
8. American Association of Clinical Endocrinologists Acromegaly Guidelines Task Force. Medical guidelines for clinical practice for the diagnosis and treatment of acromegaly – 2011 update. Endocr Pract. 2011;17(suppl 4):1-44.
9. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed November 7, 2025.
10. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2025. http://online.lexi.com. Accessed November 7, 2025.

11. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology®: Neuroendocrine and Adrenal Tumors. Version 3.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf. Accessed November 7, 2025.
12. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology®: Palliative Care. Version 1.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/palliative.pdf. Accessed November 17, 2025.
13. Fried M. Octreotide in the treatment of refractory diarrhea. Digestion. 1999,60:42-46.
14. Thapar K, Kovacs K, Stefaneanu L, et al: Antiproliferative effect of the somatostatin analogue octreotide on growth hormone-producing pituitary tumors: Results of a multicenter randomized trial. Mayo Clin Proc. 1997;72:893-900.
15. Iyer K, DiBaise JK, Rubio-Tapia A. AGA Clinical Practice Update on Management of Short Bowel Syndrome: Expert Review. Clin Gastroenterol Hepatol. 2022;20(10):2185-2194.
16. Peeters M, Van den Brande J, Francque S. Diarrhea and the rationale to use Sandostatin. Acta Gastroenterol Belg. 2010;73(1):25-36.
17. Machado NO. Pancreatic fistula after pancreatectomy: Definitions, risk factors, preventive measures, and management – Review. Int J Surg Oncol. 2012;2012:602478.