Reference number(s)
5260-A

Jurisdiction Specific Medicare Part B octreotide acetate for injectable suspension-Sandostatin LAR

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 LAR Depot	octreotide acetate for injectable suspension
octreotide acetate for injectable suspension	octreotide acetate for injectable suspension

Covered Uses

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

- The FDA-labeled indications and recognized compendial (off-label) uses are below[1-6]:
  - Acromegaly
  - Malignant carcinoid syndrome
  - Vasoactive Intestinal Peptide Tumors (VIPomas)
  - Chemotherapy-induced diarrhea (CID)
  - Pheochromocytoma and paraganglioma
  - Thymomas
  - Neuroendocrine and adrenal tumors
  - Zollinger-Ellison syndrome
  - Sulfa urea induced hypoglycemia
  - Meningioma
  - Bowel obstruction due to peritoneal carcinomatosis
  - Postgastrectomy dumping syndrome

  - Hepatocellular carcinoma
  - Merkel cell carcinoma
- Compendial Uses - ICD-10 codes supported by the Medicare Administrative Contractor[1,2]:

  The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria[1-6]

Acromegaly

Authorization of 12 months may be granted for treatment of acromegaly when all of the following criteria are met:

- The goal of treatment is to reduce growth hormone and IGF-1 levels to normal.
- Member had an inadequate response to surgery and/or radiotherapy, or surgery and/or radiotherapy is not an option.
- Member has been shown to respond to and can tolerate short-acting subcutaneous octreotide acetate.

Malignant Carcinoid Syndrome

Authorization of 12 months may be granted for symptomatic treatment of severe diarrhea and flushing associated with malignant carcinoid syndrome when initial treatment with short-acting, subcutaneous octreotide acetate has been effective and tolerated.

Vasoactive Intestinal Peptide Tumors (VIPomas)

Authorization of 12 months may be granted for symptomatic treatment of profuse watery diarrhea associated with VIP-secreting tumors when initial treatment with short-acting, subcutaneous octreotide acetate has been effective and tolerated.

Chemotherapy-Induced Diarrhea (CID)

Authorization of 12 months may be granted for treatment of chemotherapy-induced diarrhea when all of the following criteria are met:

- Oral antidiarrheal medications, such as loperamide, have become ineffective.

- Initial treatment with short-acting, subcutaneous octreotide acetate has been effective and tolerated.

Pheochromocytoma and Paraganglioma

Authorization of 12 months may be granted for treatment of pheochromocytoma/paraganglioma when initial treatment with short-acting, subcutaneous octreotide acetate has been effective and tolerated.

Thymomas

Authorization of 12 months may be granted for treatment of thymomas when initial treatment with short-acting, subcutaneous octreotide acetate has been effective and tolerated.

Neuroendocrine Tumors

Authorization of 12 months may be granted for treatment of neuroendocrine tumors when initial treatment with short-acting, subcutaneous octreotide acetate has been effective and tolerated.

Zollinger-Ellison Syndrome

Authorization of 12 months may be granted for treatment of Zollinger-Ellison syndrome when initial treatment with short-acting, subcutaneous octreotide acetate has been effective and tolerated.

Sulfa Urea Induced Hypoglycemia

Authorization of 1 month may be granted for treatment of sulfa urea induced hypoglycemia when initial treatment with short-acting, subcutaneous octreotide acetate has been effective and tolerated.

Meningiomas

Authorization of 12 months may be granted for treatment of meningiomas when initial treatment with short-acting, subcutaneous octreotide acetate has been effective and tolerated, and member has surgically inaccessible recurrent or progressive disease.

Bowel Obstruction Due to Peritoneal Carcinomatosis

Authorization of 12 months may be granted for treatment of bowel obstruction due to peritoneal carcinomatosis when initial treatment with short-acting, subcutaneous octreotide acetate has been effective and tolerated.

Postgastrectomy Dumping Syndrome

Authorization of 12 months may be granted for treatment of postgastrectomy dumping syndrome when initial treatment with short-acting, subcutaneous octreotide acetate has been effective and tolerated.

Hepatocellular Carcinoma

Authorization of 12 months may be granted for treatment of hepatocellular carcinoma when initial treatment with short-acting, subcutaneous octreotide acetate has been effective and tolerated.

Merkel Cell Carcinoma

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

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

All Other Indications

Authorization of 12 months may be granted for treatment of all other approvable indications listed in LCA A56531 when initial treatment with short-acting, subcutaneous octreotide acetate has been effective and tolerated.

Dosage and Administration

Services performed for excessive frequency are not medically necessary. Frequency is considered excessive when services are performed more frequently than generally accepted by peers and the reason for additional services is not justified by documentation.

References

1. Octreotide Acetate for Injectable Suspension (Sandostatin® LAR Depot) (L33438) Version R15. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed November 18, 2025.
2. Billing and Coding: Octreotide Acetate for Injectable Suspension (Sandostatin® LAR Depot) (A56531) Version R8. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed November 18, 2025.

3. Sandostatin LAR Depot [package insert]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; July 2024.
4. Octreotide acetate for injectable suspension. Parsippany, NJ: Teva Pharmaceuticals; July 2024.
5. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed November 7, 2025.
6. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: http://www.micromedexsolutions.com. Accessed November 17, 2025.

