

octreotide (Sandostatin IV or LAR Depot)

Medical Benefit Drug Policy

For oncology-related indications, coverage will be made based on medical necessity. Medical necessity determinations are made based on U.S. Food and Drug Administration (FDA) labeling, peer-reviewed medical literature, Medi-Cal coverage guidelines, and Centers for Medicare & Medicaid Services (CMS) approved compendia support (i.e., Clinical Pharmacology, National Comprehensive Cancer Network® (NCCN), American Hospital Formulary Service Drug Information, Thomson Micromedex DrugDex,® and Lexicomp®).

Place of Service

Sandostatin IV

Home Infusion Administration
Hospital Administration
Infusion Center Administration
Outpatient Facility Infusion Administration

Sandostatin LAR Depot - IM only

Home Infusion Administration
Hospital Administration
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: HORMONAL AGENTS, SUPPRESSANT (ADRENAL OR PITUITARY)

Mechanism of Action: Octreotide is a synthetic polypeptide structurally and pharmacologically related to somatostatin (growth hormone [somatropin] release inhibiting factor)

HCPCS:

J2353:Injection, octreotide, depot form for intramuscular injection, 1 mg

J2354:Injection, octreotide, non-depot form for subcutaneous or intravenous injection, 25 mcg

How Supplied:

- Sandostatin:
 - 50 mcg, 100 mcg, or 500 mcg single-dose 1 mL ampuls
 - 1000 mcg or 5000 mcg multi-dose vial
- Sandostatin LAR: 10 mg, 20 mg or 30 mg single-use vials

Condition(s) listed in policy (*see coverage criteria for details*)

- Acromegaly
- AIDS-Associated Diarrhea
- Bleeding Esophageal Varices

- Chemotherapy-Induced Diarrhea, treatment
- Cryptosporidiosis
- Dumping Syndrome
- Lymphorrhagia
- Malignant Intestinal Obstruction
- Pancreatitis, necrotizing
- Pituitary Adenomas (TSH-Secreting)
- Polycystic Ovary Syndrome (PCOS)
- Prevention of Postoperative Complications of Pancreatic Surgery
- Radiation-Induced Diarrhea
- Zollinger-Ellison Syndrome (Gastrinoma)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Acromegaly

Meets medical necessity if all the following are met:

1. Being prescribed by or recommended by an endocrinologist

Covered Doses:

Sandostatin IV: Up to 1500 mcg per day

Sandostatin LAR Depot IM: Up to 40 mg every 4 weeks

Coverage Period:

Sandostatin IV:

Initial: 2 weeks then reassess response

Reauthorization: Every 6 months depending on patient response

Sandostatin LAR Depot IM: indefinitely

ICD-10:

E22.0, E34.4

AIDS-Associated Diarrhea

Meets medical necessity if all the following are met:

1. Patient is currently stable on an anti-retroviral therapy (ART) regimen for ≥ 1 month
2. Provider attestation for infectious cause for diarrhea symptoms or other treatable causes (e.g. malabsorption, underlying GI disease requiring treatment) have been ruled out
3. Patient has inadequate response, intolerance, or contraindication to regular use of generic Lomotil or loperamide (OTC)
4. Patient has inadequate response, intolerance, or contraindication to Mytesi (crofelemer)

Covered Doses:

Sandostatin IV: Up to 1500 mcg/day

Sandostatin LAR IM: Up to 40 mg every 4 weeks

Coverage Period:

Yearly dependent upon patient response

ICD-10:

K52.2, K52.89, R19.7 + HIV infection B20 or B97.35

Bleeding Esophageal Varices

Meets medical necessity if all the following are met:

Covered Doses:

Sandostatin IV: Up to 1200 mcg/day

Sandostatin LAR IM: Up to 40 mg every 4 weeks

Coverage Period:

Yearly

ICD-10:

I85.01-I85.11

Chemotherapy-Induced Diarrhea, treatment

Meets medical necessity if all the following are met:

Covered Doses:

Sandostatin IV: up to 6000 mcg/ day

Sandostatin LAR: up to 40 mg every 4 weeks

Coverage Period:

Yearly

ICD-10:

Encounter Code for Chemotherapy Z51.11 + Diarrhea K52.2, K52.89, or R19.7; OR J9XXX + K52.2, K52.89, or R19.7

Cryptosporidiosis

Meets medical necessity if all the following are met:

Covered Doses:

Sandostatin IV: Up to 2400 mcg/day

Coverage Period:

Yearly

ICD-10:

A07.2

Dumping Syndrome

Meets medical necessity if all the following are met:

Covered Doses:

Sandostatin IV: Up to 600 mcg/day

Sandostatin LAR IM: Up to 20 mg every 4 weeks

Coverage Period:

Yearly

ICD-10:

K91.1

Lymphorrhagia

Meets medical necessity if all the following are met:

Covered Doses:

Sandostatin IV: Up to 300 mcg/day

Coverage Period:

Yearly

ICD-10:

R59

Malignant Intestinal Obstruction

Meets medical necessity if all the following are met:

Covered Doses:

Sandostatin IV: up to 900 mcg per day

Sandostatin LAR IM: Up to 40 mg every 4 weeks

Coverage Period:

Yearly

ICD-10:

K50.012-K56.69

Pancreatitis, necrotizing

Meets medical necessity if all the following are met:

Covered Doses:

Sandostatin IV: up to 1200 mcg/ day

Coverage Period:

Yearly

ICD-10:

K85.91, K85.92

Pituitary Adenomas (TSH-Secreting)

Meets medical necessity if all the following are met:

Covered Doses:

Sandostatin IV: up to 1500 mcg/day

Sandostatin LAR IM: Up to 40 mg every 4 weeks

Coverage Period:

Yearly

ICD-10:

E23.6

Polycystic Ovary Syndrome (PCOS)

Meets medical necessity if all the following are met:

Covered Doses:

Sandostatin IV: up to 300 mcg/ day

Coverage Period:

Yearly

ICD-10:

E28.2

Prevention of Postoperative Complications of Pancreatic Surgery

Meets medical necessity if all the following are met:

1. Being used to prevent complications of pancreatic surgery (i.e., abscess formation, sepsis, acute pancreatitis, pancreatic fistula, and peripancreatic fluid collection)

Covered Doses:

Sandostatin IV: Up to 300 mcg per day

Coverage Period:

Sandostatin IV:

Initial: 2 weeks then reassess response

Reauthorization: Every 6 months depending on patient response

ICD-10:

BF1, ODB, ODJ, OWJ, OF1, OF5, OF7, OF8, OF9, OFB, OFC, OFF, OFH, OFJ, OFL, OFM, OFP-OFW

Radiation-Induced Diarrhea

Meets medical necessity if all the following are met:

Covered Doses:

Sandostatin IV: up to 600 mcg/ day

Sandostatin LAR: up to 40 mg intramuscularly every 4 weeks

Coverage Period:

Yearly

ICD-10:

Encounter for radiotherapy Z51.0, with Diarrhea: K52.2, K52.89, R19.7 OR Effects of radiation, unspecified: T66XXA

Zollinger-Ellison Syndrome (Gastrinoma)

Meets medical necessity if all the following are met:

Covered Doses:

Sandostatin IV: up to 2000 mcg/day

Sandostatin LAR IM: Up to 60 mg every 4 weeks

Coverage Period:

Yearly

ICD-10:

D3A.092, E16.4

References

1. AHFS. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. National Comprehensive Cancer Network. Neuroendocrine and Adrenal Tumors (Version 2.2025). Available at <http://www.nccn.org>.
4. National Comprehensive Cancer Network. Palliative Care (Version 2.2025). Available at <http://www.nccn.org>.
5. Scarpellini E, Arts J, Karamanolis G, et al. International consensus on the diagnosis and management of dumping syndrome. *Nat Rev Endocrinol*. 2020 Aug;16(8):448-466. doi: 10.1038/s41574-020-0357-5. Epub 2020 May 26.
6. National Institute of Diabetes and Digestive and Kidney Diseases. Treatment of Dumping Syndrome. <https://www.niddk.nih.gov/health-information/digestive-diseases/dumping-syndrome/treatment>. Accessed August 15, 2025.
7. Sandostatin LAR Depot (octreotide injection suspension) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2024.
8. Sandostatin (octreotide injection solution) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2024.
9. Yavuz MN, Yavuz AA, Aydin F, et al: The efficacy of octreotide in the therapy of acute radiation- induced diarrhea: a randomized controlled study. *Int J Radiat Oncol Biol Phys* 2002; 54(1):195-202.

Review History

Date of Last Annual Review: 4Q2025

Changes from previous policy version:

- No clinical changes following annual review
- For oncology-related indications, coverage will be made based on medical necessity

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*