

octreotide depot (Sandostatin LAR)

Medicare Part B Drug Policy

- Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category).
- Medicare Benefit Policy Manual - Pub. 100-02, Chapter 15, Section 50, describes national policy regarding Medicare guidelines for coverage of drugs and biologicals.
- Blue Shield of California (BSC) follows Medicare statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and policy articles for determining coverage for Part B drug requests when applicable.
- BSC Medicare Part B Drug Policies will be used when coverage criteria are not fully established or there is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs.

Drug Details

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

Mechanism of Action: 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

How Supplied:

Single-use kits containing a 6-mL vial of 10 mg, 20 mg or 30 mg strength, a syringe containing 2 mL of diluent, one vial adapter, and one sterile 1½" 20 gauge safety injection needle.

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

- [Acromegaly](#)
- [Carcinoid Syndrome](#)
- [Central Nervous System Cancers \(Meningiomas\)](#)
- [Chemotherapy-Induced Diarrhea-Treatment](#)
- [Dumping Syndrome](#)
- [Malignant Intestinal Obstruction](#)
- [Neuroendocrine Tumors of the Pancreas](#)
- [Neuroendocrine Tumors: GI Tract, Lung, and Thymus](#)
- [Pheochromocytoma and Paraganglioma, Advanced](#)
- [Radiation-Induced Diarrhea](#)
- [Thymoma](#)
- [Vasoactive Intestinal Peptide Tumors](#)
- [Zollinger-Ellison Syndrome / GASTINOMA](#)

Any request for a condition not listed in policy must meet the definition of a medically accepted indication. Section 1861(t)(2)(B) of the Act defines "medically-accepted indication," as any use of a prescription drug or biological product which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included (or approved for inclusion) in one or more of the CMS approved compendia.

Special Instructions and Pertinent Information

Blue Shield of California is an independent member of the Blue Shield Association

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Y0118_24_675A1_C 10162024

H2819_24_675A1_C Accepted 10212024

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.

J2354 Sandostatin non-depot given by subcutaneous injection: This is on Noridian's Self-Administered Drug Exclusion list and only covered under Part D

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:

Up to 40 mg every 4 weeks

Coverage Period:

yearly dependent upon patient response

ICD-10:

E22.0, E34.4

Carcinoid Syndrome

Meets medical necessity if all the following are met:

Covered Doses:

Up to 40 mg every 4 weeks

Coverage Period:

yearly dependent upon patient response

ICD-10:

E34.0

Central Nervous System Cancers (Meningiomas)

Meets medical necessity if all the following are met:

1. Being used in combination with everolimus
2. Disease is progressive or considered unresectable

Covered Doses:

Up to 30 mg every 4 weeks

Coverage Period:

yearly dependent upon patient response

ICD-10:

C70.0, C70.1, C70.9, D32.0, D32.1, D32.9, D42.0, D42.1, D42.9, Z85.841, Z85.848

Chemotherapy-Induced Diarrhea-Treatment

Meets medical necessity if all the following are met:

Covered Doses:

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up to 40 mg every 4 weeks

Coverage Period:

yearly dependent upon patient response

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

Dumping Syndrome

Meets medical necessity if all the following are met:

Covered Doses:

Up to 666 mcg/day

Coverage Period:

yearly dependent upon patient response

ICD-10:

K91.1

Malignant Intestinal Obstruction

Meets medical necessity if all the following are met:

Covered Doses:

Up to 40 mg every 4 weeks

Coverage Period:

yearly dependent upon patient response

ICD-10:

K50.012-K56.69

Neuroendocrine Tumors of the Pancreas

Meets medical necessity if all the following are met:

Covered Doses:

Up to 60 mg every 4 weeks

Coverage Period:

yearly dependent upon patient response

ICD-10:

C25.4, E08.649, E16.0, E16.1, E16.3, E16.8, Z85.068, Z85.07, Z85.09, Z85.858, Z85.020, Z85.030, Z85.040, Z85.060, Z85.110, Z85.230, Z85.520, Z85.821

Neuroendocrine Tumors: GI Tract, Lung, and Thymus

Meets medical necessity if all the following are met:

Covered Doses:

Up to 60 mg every 4 weeks

Coverage Period:

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ICD-10:

C7A.010-012, C7A.019, C7A.029, C7A.020-026, C7A.00, C7A.090-096, C7A.098, C7A.1, C7A.8, D3A.019, D3A.010-12, D3A.029, D3A.020-026, D3A.00, D3A.8, D3A.090-092, D3A.094-096, C7B.00-04, C7B.09, C7B.8, E34.0, Z85.020, Z85.030, Z85.040, Z85.060, Z85.110, Z85.230, Z85.520, Z85.821

Pheochromocytoma and Paraganglioma, Advanced

Meets medical necessity if all the following are met:

Covered Doses:

Up to 30 mg intramuscularly every 4 weeks

Coverage Period:

yearly dependent upon patient response

ICD-10:

C74.10-C74.12, C74.90-C74.92, C75.5, C7B.8, Z85.858

Radiation-Induced Diarrhea

Meets medical necessity if all the following are met:

Covered Doses:

Up to 30 mg intramuscularly every 4 weeks

Coverage Period:

yearly dependent upon patient response

ICD-10:

Encounter for radiotherapy Z51.0, with Diarrhea: K52.2, K52.89, R19.7 OR Effects of radiation, unspecified: T66XXXA

Thymoma

Meets medical necessity if all the following are met:

Covered Doses:

Up to 40 mg every 4 weeks

Coverage Period:

Initial

Cover 2 months, then reassess patient response

Maintenance: Every 6 months dependent upon patient response

ICD-10:

C37, C7A.091, D1

Vasoactive Intestinal Peptide Tumors

Meets medical necessity if all the following are met:

Covered Doses:

Up to 60 mg every 4 weeks

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Coverage Period:

yearly dependent upon patient response

ICD-10:

C26.9

Zollinger-Ellison Syndrome / Gasterinoma

Meets medical necessity if all the following are met:

Covered Doses:

Up to 60 mg every 4 weeks

Coverage Period:

yearly dependent upon patient response

ICD-10:

D3A.092, E16.4

Additional Information**Summary of Evidence**

The contents of this policy were created after examining the following resources:

1. The prescribing information for Sandostatin LAR
2. CMS approved compendium in accordance with the accepted compendia ratings listed:
 - a. Micromedex DrugDex - Class I, Class IIa, of Class IIb
 - b. American Hospital Formulary Service-Drug Information (AHFS-DI) - supportive narrative text
 - c. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium - Category 1 or 2A
 - d. Lexi-Drugs - "Use: Off-Label" and rated as "Evidence Level A"
 - e. Clinical Pharmacology - supportive narrative text
3. Noridian Healthcare Solutions Medicare: Drugs, Biologics and Injections
4. NCCN Guideline: Thymomas and Thymic Carcinomas
5. NCCN Guideline: Central Nervous System Cancers
6. NCCN Guideline: Neuroendocrine and Adrenal Tumors
7. NCCN Guideline: Palliative Care
8. International Consensus on the Diagnosis and Management of Dumping Syndrome (2020).

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Sandostatin LAR are covered in addition to the following:

- Central Nervous System Cancers (Meningiomas)
- Chemotherapy-Induced Diarrhea-Treatment
- Dumping Syndrome
- Malignant Intestinal Obstruction
- Neuroendocrine Tumors of the Pancreas
- Neuroendocrine Tumors: GI Tract, Lung, and Thymus
- Pheochromocytoma and Paraganglioma, Advanced
- Radiation-Induced Diarrhea

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- Thymoma
- Zollinger-Ellison Syndrome / Gastrinoma

Explanation of Rationale:

- Support for FDA-approved indications can be found in the manufacturer’s prescribing information.
- Beginning January 1, 2019, the Centers for Medicare & Medicaid Services (CMS) provided Medicare Advantage (MA) plans the option of applying step therapy for physician-administered and other Part B drugs to lower costs and improve the quality of care for Medicare beneficiaries.
- Support for the listed indications is found in the National Comprehensive Cancer Network’s (NCCN) Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drug and biologic medications in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).
 - Central Nervous System Cancers (Meningiomas)
 - Chemotherapy-Induced Diarrhea-Treatment
 - Malignant Intestinal Obstruction
 - Neuroendocrine Tumors of the Pancreas
 - Neuroendocrine Tumors: GI Tract, Lung, and Thymus
 - Pheochromocytoma and Paraganglioma, Advanced
 - Radiation-Induced Diarrhea
 - Thymoma
 - Zollinger-Ellison Syndrome / Gastrinoma / Glucagonoma / Insulinoma
- Support for using Sandostatin LAR for Dumping Syndrome is found in the International Consensus on the Diagnosis and Management of Dumping Syndrome (2020). These evidence-based guidelines support the use of somatostatin analogues as the preferred treatment option for patients with well-established dumping syndrome who do not respond to initial dietary modifications (with or without acarbose treatment); varying support is available for both short-acting and long-acting formulations of octreotide. Furthermore, on its Treatment of Dumping Syndrome Health Information resource page, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) supports the use of both subcutaneous and intramuscular octreotide to help reduce the symptoms of dumping syndrome.

References

1. CMS Benefit Policy Manual. Chapter 15; § 50 Drugs and Biologicals
2. Medicare Coverage Database. Available at <https://www.cms.gov/Medicare-Coverage-Database/search.aspx>
3. Social Security Act (Title XVIII) Standard References, Sections: 1862(a)(1)(A) Medically Reasonable & Necessary; 1862(a)(1)(D) Investigational or Experimental; 1833(e) Incomplete Claim; 1861(t) (1) Drugs and Biologicals
4. AHFS. Available by subscription at <http://www.lexi.com>
5. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
6. National Comprehensive Cancer Network. Central Nervous System Cancers (Version 4.2024). Available at <http://www.nccn.org>.

7. National Comprehensive Cancer Network. Neuroendocrine and Adrenal Tumors (Version 4.2024). Available at <http://www.nccn.org>.
8. National Comprehensive Cancer Network. Palliative Care (Version 1.2025). Available at <http://www.nccn.org>.
9. National Comprehensive Cancer Network. Thymomas and Thymic Carcinomas (Version 1.2025). Available at <http://www.nccn.org>.
10. National Comprehensive Cancer Network. Merkel Cell Carcinoma (Version 1.2025). Available at <http://www.nccn.org>.
11. 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.
12. 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 February 14, 2025.
13. Sandostatin LAR Depot (octreotide acetate) Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 7/2024
14. 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.
15. Loehrer PJ, Wang W, Johnson DH, et al. Octreotide alone or with prednisone in patients with advanced thymoma and thymic carcinoma: an Eastern Cooperative Oncology Group Phase II Trial. *J Clin Oncol* 2004;22(2):293-9.
16. 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.
17. Chamberlain MC, Glantz MJ. Recurrent meningioma: salvage therapy with long-acting somatostatin analogue. *Neurology* 2007;69-969-973.
18. Johnson DR, et al. Phase II study of subcutaneous octreotide in adults with recurrent or progressive meningioma and meningeal hemangiopericytoma. *Neuro Oncol* 2011;13:530-535.
19. Benson AB, et al. Recommended Guidelines for the treatment of cancer therapy induced diarrhea. *J Clin Oncol* 22:2918-2926.

Review History

Date of Last Annual Review: 1Q2025

Changes from previous policy version:

- New Part B policy

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

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