Effective Date 12/1/2023
Next Review Date 12/1/2024
Coverage Policy Number IP0489

Sandostatin LAR Depot (Non-Oncology Indications)

Table of Contents

Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for Sandostatin® LAR Depot (octreotide acetate) intramuscular injection.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Sandostatin® LAR Depot (octreotide acetate) intramuscular injection is considered medically necessary when ONE of the following is met (1, 2, 3, 4, 5, 6, or 7):

1. **Acromegaly.** Individual meets **ALL** of the following criteria (A, B, C, and D):
   A. Individual meets **ONE** of the following (i, ii, or iii):
      i. Inadequate response to surgery and/or radiotherapy

ii. NOT an appropriate candidate for surgery and/or radiotherapy
iii. Experiencing negative effects due to tumor size (for example, optic nerve compression)

B. Individual has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory

Pre-treatment (baseline) refers to the IGF-1 level prior to the initiation of any somatostatin analog (for example, Mycapssa [octreotide delayed-release capsules], an octreotide acetate injection product [for example, Bynfezia Pen, Sandostatin {generic}, Sandostatin LAR Depot], Signifor LAR [pasireotide injection], Somatuline Depot [lanreotide injection], dopamine agonist [for example, cabergoline, bromocriptine], or Somavert [pegvisomant injection]). Reference ranges for IGF-1 vary among laboratories.

C. The medication is prescribed by, or in consultation with, an endocrinologist

D. Individual meets the preferred covered alternative(s) criteria as indicated in the table below.

Dosing. Approve up to 40 mg administered intramuscularly no more frequently than once every 4 weeks.

2. **Gastroesophageal variceal hemorrhage, acute.**

3. **Diarrhea associated with chemotherapy or radiation.** Individual meets **EITHER** of the following criteria (A or B):
   A. Individual has Grade 1 or 2 diarrhea and has failed an antimotility medication
   B. Individual has Grade 3 or 4 diarrhea

4. **Enterocutaneous fistula.**

5. **Perioperative management of individuals undergoing pancreatic resection (including fistula).**

6. **Thyroid-stimulating hormone (TSH)-secreting pituitary adenoma.** Individual meets the following criterion (A):
   A. Surgical resection has been incomplete.

7. **Secretory diarrhea in acquired immune deficiency syndrome (AIDS).** Individual meets the following criterion (A):
   A. Inadequate response to antimicrobial or antimotility agents.

Coverage varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.

Employer Group Non-Covered Products and the Preferred Covered Alternatives:

Non-Covered Product	Criteria
Sandostatin LAR Depot (octreotide acetate) for intramuscular injection	For a diagnosis of **Acromegaly** only. There is documentation of **ONE** of the following (A or B): A. Individual has previously started on or is currently receiving Sandostatin LAR Depot (octreotide acetate) injection. B. Individual has had an inadequate response, contraindication, or is intolerant to Somatuline Depot (lanreotide acetate) injection.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Sandostatin LAR Depot (octreotide acetate) is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration:

- Acromegaly: up to 12 months
- Gastroesophageal variceal hemorrhage, acute: one time
- Diarrhea associated with chemotherapy or radiation: one time
- Enterocutaneous fistula: up to 12 months
- Perioperative management of individuals undergoing pancreatic resection (including fistula): one time
- Thyroid-stimulating hormone (TSH)-secreting pituitary adenoma: up to 12 months
- Secretory diarrhea in acquired immune deficiency syndrome (AIDS): up to 12 months

Reauthorization approval duration:

- Acromegaly: up to 12 months
- Gastroesophageal variceal hemorrhage, acute: not applicable for continuation beyond initial approval duration
- Diarrhea associated with chemotherapy or radiation: not applicable for continuation beyond initial approval duration
- Enterocutaneous fistula: up to 12 months
- Perioperative management of individuals undergoing pancreatic resection (including fistula): not applicable for continuation beyond initial approval duration
- Thyroid-stimulating hormone (TSH)-secreting pituitary adenoma: up to 12 months
- Secretory diarrhea in acquired immune deficiency syndrome (AIDS): up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Coding

1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J2353	Injection, octreotide, depot form for intramuscular injection, 1 mg

Background

OVERVIEW

Sandostatin LAR Depot, a somatostatin analog, is indicated for the following uses:[1]

- **Acromegaly**, in 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 growth hormone and insulin-like growth factor-1 levels to normal.

- **Carcinoid tumors**, in patients with severe diarrhea and flushing episodes associated with metastatic carcinoid tumors.
- **Vasoactive intestinal peptide tumors (VIPomas)**, in patients with profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors.

Guidelines
National Comprehensive Cancer Network (NCCN) guidelines support use of Sandostatin LAR Depot in multiple conditions:

- **Central Nervous System Cancers:** Guidelines (version 1.2023 – March 24, 2023) recommend Sandostatin LAR Depot for the treatment of meningiomas that recur despite surgery and/or radiation therapy, or are not amenable to treatment with surgery or radiation therapy.[2]
- **Neuroendocrine and Adrenal Tumors:** Guidelines (version 1.2023 – August 2, 2023) recommend Sandostatin LAR Depot for the management of carcinoid syndrome; tumors of the gastrointestinal tract, lung, thymus (carcinoid tumors), and pancreas (including glucagonomas, gastrinomas, VIPomas, insulinomas); pheochromocytomas; and paragangliomas.[3] Patients who have local unresectable disease and/or distant metastases and clinically significant tumor burden or progression should be started on therapy with a somatostatin analog to potentially control tumor growth. The North American Neuroendocrine Tumor Society (NANETS) consensus guidelines for the surveillance and medical management of midgut NETs (2017) also recommend Sandostatin LAR Depot as a first-line initial therapy in most patients with metastatic midgut NETs for control of carcinoid syndrome and inhibition of tumor growth.[4]
- **Thymomas and Thymic Carcinomas:** Guidelines (version 1.2023 – December 15, 2022) recommend Sandostatin LAR Depot as a therapy option with or without concomitant prednisone therapy.[5] In patients with thymoma who have positive octreotide scan or symptoms of carcinoid syndrome, octreotide therapy may be useful.

Dosing and Availability
Patients Not Currently Receiving Sandostatin Injection Subcutaneously:

- Acromegaly: 50 mcg three times daily Sandostatin Injection subcutaneously for 2 weeks followed by Sandostatin LAR Depot 20 mg intragluteally every 4 weeks for 3 months
- Carcinoid Tumors and VIPomas: Sandostatin Injection subcutaneously 100 to 600 mcg/day in 2-4 divided doses for 2 weeks followed by Sandostatin LAR Depot 20 mg every 4 weeks for 2 months

Patients Currently Receiving Sandostatin Injection Subcutaneously:

- Acromegaly: 20 mg every 4 weeks for 3 months
- Carcinoid Tumors and VIPomas: 20 mg every 4 weeks for 2 months

Renal Impairment, Patients on Dialysis: 10 mg every 4 weeks

Hepatic Impairment, Patients With Cirrhosis: 10 mg every 4 weeks

For injectable suspension: strengths 10 mg per 6 mL, 20 mg per 6 mL, or 30 mg per 6 mL vials

References

1. Sandostatin® LAR Depot intramuscular injection [prescribing information]. East Hanover, NJ: Novartis; July 2023.
2. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 1.2023 – March 24, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 28, 2023.
3. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 1.2023 – August 2, 2023). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 17, 2023.
4. Strosberg JR, Halfdanarson TR, Bellizi AR, et al. The North American Neuroendocrine Tumor Society consensus guidelines for surveillance and medical management of midgut neuroendocrine Tumors. *Pancreas*. 2017;46(6):707-714.
5. The NCCN Thymomas and Thymic Carcinomas Clinical Practice Guidelines in Oncology (version 1.2023 – December 15, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 28, 2023.

Supplemental References

1. Gurusamy KS, Koti R, Fusai G, et al. Somatostatin analogues for pancreatic surgery. Cochrane Database of Systematic Reviews 2013, Issue 4. Art. No.: CD008370. DOI: 10.1002/14651858.CD008370.pub3
2. Becker, K.L."Clinical Applications of Somatostatin and its Analogs". Principles and Practice of Endocrinology & Metabolism. 3rd edition. Philadelphia: Lippincott Williams & Wilkins, 2001. Ovid SP. Accessed April 11, 2014
3. Benson III AB, Ajani JA, Catalano RB, et al. Recommended Guidelines for the Treatment of Cancer Treatment-Induced Diarrhea. J Clin Oncol. 2004 Jul 15; 22(14):2918-26.
4. Corley DA, Cello JP, Adkisson W, et al. Octreotide for Actue Esophageal Variceal Bleeding: A Meta-analysis. Gastroenterology 2001; 120:946-954.
5. Kuhn JM, Arlot S, Lefebvre H et al. Evaluation of the treatment of thyrotropin-secreting pituitary adenomas with a slow release formulation of the somatostatin analog lanreotide. J Clin Endocrinol Metab 2000; 85: 1487-91.