Utilization Review Policy 324

POLICY: Somatostatin Analogs – Sandostatin LAR Depot Utilization Management Medical Policy
- Sandostatin® LAR Depot (octreotide acetate intramuscular injection – Novartis)

EFFECTIVE DATE: 1/1/2024
LAST REVISION DATE: 8/16/2023

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

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.

POLICY STATEMENT

Prior Authorization is recommended for medical coverage of Sandostatin LAR Depot. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the

specialized skills required for evaluation and diagnosis of patients treated with Sandostatin LAR Depot as well as the monitoring required for adverse events and long-term efficacy, approval requires Sandostatin LAR Depot to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Sandostatin LAR Depot is recommended for requests meeting both the preferred product step therapy requirements and indication requirements:

Preferred Product Step Therapy Requirements (New Starts Only)
Criteria. *The patient must meet the following criteria (A or B):*

- **A)** For patients new to Sandostatin LAR Depot therapy only, must have a trial of Somatuline Depot prior to approval of Sandostatin LAR Depot. New starts to therapy defined as no use of Sandostatin LAR Depot within the past 180 days for Medicaid and Commercial patients. New starts to therapy defined as no use of Sandostatin LAR Depot within the past 365 days for Medicare patients.
- **B)** Patient has a contraindication or other clinical reason why Somatuline Depot cannot be tried before Sandostatin LAR Depot.

Note: Preferred product step only required for indications FDA-Approved for both Sandostatin LAR Depot and Somatuline Depot.

FDA-Approved Indications

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1. **Acromegaly.** Approve for 1 year if the patient meets the following (A, B, and C):
   - **A)** Patient meets ONE of the following (i, ii, or iii):
     - **i.** Patient has had an inadequate response to surgery and/or radiotherapy; OR
     - **ii.** Patient is NOT an appropriate candidate for surgery and/or radiotherapy; OR
     - **iii.** Patient is experiencing negative effects due to tumor size (e.g., optic nerve compression); AND
   - **B)** Patient 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; AND
     Note: Pre-treatment (baseline) refers to the IGF-1 level prior to the initiation of any somatostatin analog (e.g., Mycapssa [octreotide delayed-release capsules], an octreotide acetate injection product [e.g., Bynfezia Pen, Sandostatin {generic}, Sandostatin LAR Depot], Signifor LAR [pasireotide injection], Somatuline Depot [lanreotide injection], dopamine agonist [e.g., 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.

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

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2. **Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptides-secreting tumors [VIPomas], insulinomas).** Approve for 1 year if the medication is prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist.

Dosing. Approve up to 30 mg administered intramuscularly no more frequently than once every 4 weeks.

Other Uses with Supportive Evidence

3. Meningioma. Approve for 1 year if the medication is prescribed by or in consultation with an oncologist, radiologist, or neurosurgeon.

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

4. Pheochromocytoma and Paraganglioma. Approve for 1 year if the medication is prescribed by or in consultation with an endocrinologist, oncologist, or neurologist.

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

5. Thymoma and Thymic Carcinoma. Approve for 1 year if the medication is prescribed by or in consultation with an oncologist.

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

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Sandostatin LAR Depot is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	New UCare policy with preferred product step therapy for all lines of business.	01/01/2024