

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Somatostatin Analogs – Octreotide Long-Acting Products Utilization Management Medical Policy

- Sandostatin® LAR Depot (octreotide acetate intramuscular injection – Novartis, generic)

REVIEW DATE: 07/22/2026

OVERVIEW

Octreotide long-acting release (LAR), a somatostatin analog, is indicated for the following uses:¹

- **Acromegaly**, long-term maintenance, 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**, long-term treatment, in patients with severe diarrhea and flushing episodes associated with metastatic carcinoid tumors.
- **Vasoactive intestinal peptide (VIP) tumors (VIPomas)**, long-term treatment, in patients with profuse watery diarrhea associated with VIP-secreting tumors.

Limitations of Use: In patients with carcinoid syndrome and VIPomas, the effect of octreotide and octreotide LAR on tumor size, rate of growth and development of metastases, has not been determined.¹

Guidelines

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

- **Central Nervous System Cancers:** Guidelines (version 2.2026 – June 10, 2026) recommend octreotide LAR (single agent or in combination with everolimus) as a “Useful in Certain Circumstances” treatment option for recurrent meningiomas (category 2A recommendation).²
- **Merkel Cell Carcinoma:** Guidelines (version 2.2026 – October 24, 2025) recommend octreotide LAR as a treatment option for somatostatin-positive disease; specifically as a “Useful in Certain Circumstances” treatment option for patients with primary/recurrent regional or disseminated disease if use of a programmed death-ligand 1 (PD-L1) inhibitor or a programmed death-1 (PD-1) inhibitor is contraindicated or disease has progressed on a PD-L1 or PD-1 inhibitor monotherapy (category 2A recommendation for primary/regional disease; category 2B recommendation for disseminated disease).³ NCCN cites the following PD-L1 and PD-1 inhibitors as preferred treatment options for Merkel cell carcinoma: Bavencio® (avelumab intravenous infusion), Keytruda® (pembrolizumab intravenous infusion), Opdivo® (nivolumab intravenous infusion), Zynyz® (retifanlimab-dlwr intravenous infusion).
- **Neuroendocrine and Adrenal Tumors:** Guidelines (version 1.2026 – April 21, 2026) recommend octreotide LAR as a treatment option 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 (category 2A recommendations).⁴
- **Thymomas and Thymic Carcinomas:** Guidelines (version 2.2026 – April 10, 2026) recommend octreotide (including octreotide LAR), with or without prednisone, as a “preferred” treatment

option for octreotide scan- or dotatate PET/CT (Gallium-68 DOTA-octreotate positron emission tomography/computed tomography)-positive thymoma (category 2A recommendation).⁵

Supportive Evidence

- **Diarrhea Associated with Chemotherapy:** The Canadian Working Group on chemotherapy-induced diarrhea (2007) recommends octreotide LAR and octreotide immediate-release for the treatment of Grades 3 or 4 chemotherapy-induced diarrhea.⁶ Aggressive management with high-dose loperamide or octreotide may reduce the morbidity and mortality associated with chemotherapy-induced diarrhea and improve patient outcomes. Grade 3 diarrhea is characterized by ≥ 7 stools daily over baseline, incontinence, the need for intravenous fluids for > 24 hours, interference with activities of daily living, and may require hospitalization. Grade 4 diarrhea is when the patient is experiencing life-threatening consequences such as hemodynamic collapse.
- **Enterocutaneous Fistulas:** In case series, octreotide has been effective in patients with enterocutaneous fistulas.⁷ Octreotide when used with an acid inhibitor agent (omeprazole) reduced the output of enterocutaneous fistulas. In a retrospective trial that assessed the postoperative use of somatostatin after definitive surgery for duodenal fistula, 84 of 154 patients received a somatostatin postoperatively. Although postoperative use of somatostatin was not associated with an overall reduction of recurrent fistulas, use was associated with a reduction of recurrent high-output fistulas. The average time for fistula closure without surgical intervention ranges from 12 to 66 days.⁹
- **Pancreatic Fistulas:** In case studies and retrospective reviews, octreotide demonstrated reduction of output and fistula closure.¹⁰⁻¹² The use of octreotide also showed a reduced risk of postoperative pancreatic fistulas and hospital stay.¹² On average, pancreatic fistulas closed between 18 to 35 days.¹¹
- **Small Bowel Bleeds/Angiodysplasia Related Bleeding:** The American College of Gastroenterology guidelines for diagnosis and management of small bowel bleeding (2015) recommend somatostatin analogs (lanreotide, octreotide immediate-release, octreotide LAR) for the treatment of chronic bleeding due to vascular abnormalities of the gastrointestinal tract.¹³ Long-acting somatostatin analogs have been shown as a beneficial rescue therapy to control angiodysplasia bleeding. The OCEAN study, a multicenter randomized trial comparing standard of care with octreotide LAR for angiodysplasia-related bleeding, demonstrated that octreotide reduced the total number of transfusions compared to standard of care (11.0 transfusions vs. 21.2 transfusions, respectively).¹⁴

POLICY STATEMENT

Prior Authorization is recommended for medical coverage of octreotide LAR injection. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. 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. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with octreotide LAR injection as well as the monitoring required for adverse events and long-term efficacy, approval requires octreotide LAR injection to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

Indications and/or approval conditions noted with [\[EviCore\]](#) are managed by EviCore healthcare for those clients who use EviCore for oncology and/or oncology-related reviews. For these conditions, a prior authorization review should be directed to EviCore at www.EviCore.com.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of octreotide LAR injection is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Acromegaly.** Approve for 1 year if the patient meets ALL of 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.

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).** [\[EviCore\]](#) 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. **Diarrhea Associated with Chemotherapy.** [\[EviCore\]](#) Approve for 3 months if the patient meets ALL of the following (A, B, and C):
 - A) Patient has Grade 3 or Grade 4 diarrhea; AND
Note: Examples of Grade 3 or Grade 4 diarrhea include more than 6 bowel movements above baseline per day, colitis symptoms, interference with activities of daily living, hemodynamic instability, hospitalization, serious complications (e.g., ischemic bowel, perforation, toxic megacolon), or other colitis-related life-threatening conditions.
 - B) Patient has tried at least one antimotility medication; AND
Note: Examples of antimotility medications include loperamide and diphenoxylate.

C) The medication is prescribed by or in consultation with an oncologist or gastroenterologist.

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

4. Enterocutaneous Fistulas. Approve for 3 months.

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

5. Meningioma. [\[EviCore\]](#) 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.

6. Merkel Cell Carcinoma. [\[EviCore\]](#) Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

A) Patient is ≥ 18 years of age; AND

B) Patient has regional or distant metastatic disease; AND

C) Patient meets ONE of the following (i or ii):

i. Patient has contraindications to a programmed death-ligand 1 (PD-L1) or programmed death-1 (PD-1) inhibitor; OR

Note: PD-L1/PD-1 inhibitors include Bavencio (avelumab intravenous infusion), Keytruda (pembrolizumab intravenous infusion), and Opdivo (nivolumab intravenous infusion), Zynyz (retifanlimab-dlwr intravenous infusion).

ii. Patient has progressed on a programmed death-ligand 1 (PD-L1) or programmed death-1 (PD-1) inhibitor; AND

Note: PD-L1/PD-1 inhibitors include Bavencio (avelumab intravenous infusion), Keytruda (pembrolizumab intravenous infusion), and Opdivo (nivolumab intravenous infusion), Zynyz (retifanlimab-dlwr intravenous infusion).

D) The medication is prescribed by or in consultation with an oncologist.

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

7. Pancreatic Fistulas. Approve for 2 months if the patient is being treated for operative trauma, pancreatic resection, acute or chronic pancreatitis, or pancreatic infection.

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

8. **Pheochromocytoma and Paraganglioma.** *[EviCore]* 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.

9. **Small Bowel Bleeds/Angiodysplasia-Related Bleeding:** Approve for 6 months if the patient meets BOTH of the following: (A and B):
A) Patient has chronic, recurrent gastrointestinal bleeds lasting ≥ 3 months; AND
B) The medication is prescribed by or in consultation with a gastroenterologist.

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

10. **Thymoma and Thymic Carcinoma.** *[EviCore]* 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 octreotide LAR 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 2024.
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4. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 1.2026 – April 21, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on July 14, 2026.
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10. Alghamdi AA, Jawas AM, Hart RS. Use of octreotide for the prevention of pancreatic fistula after elective pancreatic surgery: a systematic review and meta-analysis. *Can J Surg*. 2007;50(6):459-466.
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14. Goltstein LCMJ, Grooteman KV, Bernts LHP, et al. Standard of care versus octreotide in angiodysplasia-related bleeding (the OCEAN Study): a multicenter randomized controlled trial. *Gastroenterology.* 2024;166(4):690-703.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	Merkel Cell Carcinoma: The condition Merkel cell carcinoma was added under “Other Uses with Supportive Evidence”. Diarrhea Associated with Chemotherapy: The condition diarrhea associated with chemotherapy was added under “Other Uses with Supportive Evidence”.	03/05/2025
Selected Revision	Diarrhea Associated with Chemotherapy: A note was added to provide examples of Grade 3 or Grade 4 diarrhea.	05/14/2025
Selected Revision	Small Bowel Bleeds/Angiodysplasia Related Bleeding: This condition was added under “Other Uses with Supportive Evidence”.	08/27/2025
Annual Revision	No criteria changes.	02/11/2026
Early Annual Revision	Octreotide Long-Acting Release (LAR): This term replaced “octreotide intramuscular” throughout the document. Diarrhea Associated with Chemotherapy: The specialist requirement was reworded to “The medication is prescribed by or in consultation with an oncologist or gastroenterologist”. Merkel Cell Carcinoma: “Programmed death-ligand 1 (PD-L1) or programmed death-1 (PD-1) inhibitor” replaced the term “checkpoint immunotherapy”. Zynzy (retifanlimab-dlwr intravenous infusion) was added to the Note of examples of PD-L1/PD-1 inhibitors.	07/22/2026