CARECONTINUUM™

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: 02/11/2026

OVERVIEW

Octreotide intramuscular injection, 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 octreotide intramuscular injection in multiple conditions.
- **Central Nervous System Cancers:** Guidelines (version 3.2025 – December 5, 2025) recommend octreotide intramuscular injection 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]
- **Merkel cell carcinoma** (version 2.2026 – October 24, 2025) clinical practice guidelines recommend octreotide LAR as a treatment option for patients with primary and recurrent regional disease, in-transit disease, or disseminated disease M1 who have contraindications to checkpoint immunotherapy (Bavencio® [avelumab intravenous infusion], Keytruda® [pembrolizumab intravenous infusion], and Opdivo® [nivolumab intravenous infusion]); or have progressed on checkpoint immunotherapy (category 2A for primary and recurrent regional disease and category 2B for M1 disease).[12]
- **Neuroendocrine and Adrenal Tumors:** Guidelines (version 3.2025 – October 1, 2025) recommend octreotide intramuscular injection 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 octreotide intramuscular injection 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 1.2026 – October 3, 2025) recommend octreotide intramuscular injection 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.

Supportive Evidence

- **Diarrhea Associated with Chemotherapy:** The Canadian Working Group on chemotherapy-induced diarrhea (2007) recommend octreotide LAR and octreotide immediate-release for the treatment of grades 3 or 4 chemotherapy induced diarrhea.[13] Aggressive management with high-dose loperamide or octreotide may reduce the morbidity and mortality associated with chemotherapy induced diarrhea and improve patient outcomes. Grade 1 diarrhea is when the patients is experiencing < 4 stools daily over their baseline. Grade 2 diarrhea is an increase of 4 to 6 stools daily over baseline, IV fluids may be needed; however, it is not interfering with activities of daily living. Grade 3 diarrhea is characterized by ≥ 7 stools daily over baseline, incontinence, the need for IV 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.[6] Octreotide when used with an acid inhibitor agent (omeprazole) reduced the output of enterocutaneous fistulas. The European Journal of Medical Research reported in a trial where 84 of 154 patients were divided into the somatostatin group.[7] This trial showed that postoperative use of somatostatin served as a protective factor for developing into high-output recurrent fistulas. The average time for fistula closure without surgical intervention ranges from 12 to 66 days.[11]
- **Pancreatic Fistulas:** In case studies and retrospective reviews, octreotide demonstrated reduction of output and fistula closure.[8-10] The use of octreotide also showed a reduced risk of postoperative pancreatic fistulae and hospital stay.[10] On average, pancreatic fistulas closed between 18 to 35 days.[9]
- **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 or octreotide long-acting or immediate-release) for the treatment of chronic bleeding due to vascular abnormalities of the gastrointestinal tract.[15] Long-acting somatostatin analogs has 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).[15]

POLICY STATEMENT

Prior Authorization is recommended for medical coverage of octreotide intramuscular injection. 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. 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 intramuscular injection as well as the monitoring required for adverse events and long-term efficacy, approval requires octreotide intramuscular 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 intramuscular 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 patients 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 mega-colon), 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 being 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.

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4. Enterocutaneous Fistulas. Approve for 3 months.

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

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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.

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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 checkpoint immunotherapy; OR
  Note: Checkpoint immunotherapy includes Bavencio (avelumab intravenous infusion), Keytruda (pembrolizumab intravenous infusion), and Opdivo (nivolumab intravenous infusion).
- **ii.** Patient has progressed on checkpoint immunotherapy; AND
  Note: Checkpoint immunotherapy includes Bavencio (avelumab intravenous infusion), Keytruda (pembrolizumab intravenous infusion), and Opdivo (nivolumab intravenous infusion).

D. 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.

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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.

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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.

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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.

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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 intramuscular injection 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.
2. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 3.2025 – December 5, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 29, 2026.
3. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 3.2025 – October 1, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 29, 2026.
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 1.2026 – October 3, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 29, 2026.
6. Kong X, Cao Y, Yang D, Zhang X. Continuous irrigation and suction with a triple-cavity drainage tube in combination with sequential somatostatin-somatotropin administration for the management of postoperative high-output enterocutaneous fistulas: Three case reports and literature review. *Medicine*. 2019;98(46):e18010.
7. Tian W, Zhao R, Luo S, et al. Effect of postoperative utilization of somatostatin on clinical outcome after definitive surgery for duodenal fistula. *Eur J Med Res*. 2023;28(1):63.
8. 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.
9. Veillette G, Dominguez I, Ferrone C, et al. Implications and management of pancreatic fistulas following pancreaticoduodenectomy: the Massachusetts General Hospital experience. *Arch Surg*. 2008;143(5):476-481.
10. Sundaram S, Patra BR, Choksi D, et al. Outcomes and predictors of response to endotherapy in pancreatic ductal disruptions with refractory internal and high-output external fistulae. *Ann Hepatobiliary Pancreat Surg*. 2022;26(4):347-354.
11. Noori I. Postoperative enterocutaneous fistulas: Management outcomes in 23 consecutive patients. *Ann Med Surg*. 2021;66:102413.
12. The NCCN Merkel Cell Carcinoma Clinical Practice Guidelines (version 2.2026 – October 24, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 29, 2026.
13. Maroun JA, Anthony LB, Blais N, et al. Prevention and management of chemotherapy-induced diarrhea in patients with colorectal cancer: a consensus statement by the Canadian Working Group on Chemotherapy-Induced Diarrhea. *Curr Oncol*. 2007;14(1):13-20.

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14. Gerson LB, Fidler JL, Cave DR, Leighton JA. ACG clinical guideline: diagnosis and management of small bowel bleeding. *Am J Gastroenterol*. 2015;110(9):1265-1288.
15. 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
Annual Revision	No criteria changes.	05/15/2024
Selected Revision	**Enterocutaneous Fistulas:** The condition enterocutaneous fistulas was added under "Other Uses with Supportive Evidence". **Pancreatic Fistulas.** The condition pancreatic fistulas was added under "Other Uses with Supportive Evidence".	08/07/2024
Selected Revision	Policy name changed from Somatostatin Analogs – Sandostatin LAR Depot Utilization Management Medical Policy to Somatostatin Analogs – Octreotide Long-Acting Products Utilization Management Medical Policy. The generic octreotide intramuscular injection was added, where relevant, throughout the policy.	11/13/2024
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