

PRIOR AUTHORIZATION POLICY

- POLICY:** Somatostatin Analogs – Octreotide Long-Acting Products Prior Authorization Policy
- Sandostatin[®] LAR Depot (octreotide acetate intramuscular injection – Novartis, generic)

REVIEW DATE: 05/15/2024; selected revision 08/07/2024, 11/13/2024

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 1.2023 – March 24, 2023) 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
- **Neuroendocrine and Adrenal Tumors:** Guidelines (version 1.2023 – August 2, 2023) 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 1.2024 – November 21, 2023) 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

- **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

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- **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

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of octreotide intramuscular injection. All approvals are provided for the duration noted below. 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.

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.
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.

Other Uses with Supportive Evidence

3. **Enterocutaneous Fistulas.** Approve for three months.
4. **Meningioma.** Approve for 1 year if the medication is prescribed by or in consultation with an oncologist, radiologist, or neurosurgeon.

5. **Pancreatic Fistulas.** Approve for two months if the patient is being treated for operative trauma, pancreatic resection, acute or chronic pancreatitis, or pancreatic infection.
6. **Pheochromocytoma and Paraganglioma.** Approve for 1 year if the medication is prescribed by or in consultation with an endocrinologist, oncologist, or neurologist.
7. **Thymoma and Thymic Carcinoma.** Approve for 1 year if the medication is prescribed by or in consultation with an oncologist.

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

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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.
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