PRIOR AUTHORIZATION POLICY

POLICY: Somatostatin Analogs – Octreotide Immediate-Release Products Prior Authorization Policy
- Bynfezia Pen™ (octreotide acetate immediate-release subcutaneous injection – Sun Pharmaceutical [discontinued])
- Sandostatin® (octreotide acetate immediate-release subcutaneous or intravenous injection – Novartis, generic)

REVIEW DATE: 05/22/2024; selected revision 08/07/2024

OVERVIEW

Octreotide acetate immediate-release injection products (Bynfezia Pen, Sandostatin [generic]), somatostatin analogs, are indicated for the following uses:[1-3]

- **Acromegaly**, to reduce blood levels of growth hormone and insulin-like growth factor-1 in adults with acromegaly who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses.
- **Carcinoid tumors**, in adults with severe diarrhea and flushing episodes associated with metastatic carcinoid tumors. Studies were not designed to show an effect on the size, rate of growth, or development of metastases.
- **Vasoactive intestinal peptide (VIP) tumors**, in adults with profuse watery diarrhea associated with VIP-secreting tumors. Studies were not designed to show an effect on the size, rate of growth, or development of metastases.

Guidelines

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

- **Central Nervous System Cancers:** Guidelines (version 1.2023 – March 24, 2023) note that an octreotide scan may be used to confirm magnetic resonance imaging findings.[4] NCCN also notes that everolimus and octreotide may be useful for patients with recurrent meningiomas.
- **Neuroendocrine and Adrenal Tumors:** Guidelines (version 1.2023 – August 2, 2023) recommend octreotide 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.[5] 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.
- **Thymomas and Thymic Carcinomas:** Guidelines (version 1.2024 – November 21, 2023) note that in patients with thymoma who have positive octreotide scan or symptoms of carcinoid syndrome, octreotide therapy may be useful.[6]

Supportive Evidence

- **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. The European Journal of Medical Research reported results from a trial where 84 of 154 patients with enterocutaneous fistulas received somatostatin; 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.[12]

- **Pancreatic Fistulas:** Octreotide demonstrated reduction of output and fistula closure in case studies and retrospective reviews.[9-11] The use of octreotide also showed a reduced risk of postoperative pancreatic fistulae and hospital stay.[11] On average, pancreatic fistulas closed between 18 to 35 days.[10]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of octreotide immediate-release products. 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 immediate-release products as well as the monitoring required for adverse events and long-term efficacy, approval requires octreotide immediate-release products 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 immediate-release products 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 3 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 2 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 immediate-release products 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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4. 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 May 16, 2024.
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