MEDICAL MUTUAL®

Drug Policy

Policy:	**Somastatin Analogs – Octreotide Immediate-Release Products Prior Authorization Policy**	**Annual Review Date:** **08/24/2023**
Impacted Drugs:	Bynfezia Pen (immediate-release octreotide acetate subcutaneous injection – Sun Pharmaceutical) Sandosatatin (immediate-release octreotide acetate subcutaneous or intravenous injection – Novartis, generic)	**Last Revised Date:** **08/24/2023**

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.
- **Vasoactive intestinal peptide (VIP) tumors**, in adults with profuse watery diarrhea associated with VIP-secreting tumors.

Guidelines

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

- **Central Nervous System Cancers:** Guidelines (version 5.2020 – April 15, 2021) recommend octreotide for the treatment of meningiomas that recur despite surgery and/or radiation therapy, or are not amenable to treatment with surgery or radiation therapy.[4]
- **Neuroendocrine and Adrenal Tumors:** Guidelines (version 1.2021 – April 14, 2021) 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 1.2021 – December 4, 2020) recommend octreotide as a second-line systemic therapy option with or without concomitant prednisone therapy.[6] In patients with thymoma who have positive octreotide scan or symptoms of carcinoid syndrome, octreotide therapy may be useful.

POLICY STATEMENT

This policy involves the use of Octreotide immediate-release products. Prior authorization is recommended for pharmacy benefit coverage of Octreotide immediate-release products. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended**

for Approval are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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, initial approval requires Octreotide immediate-release products be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Octreotide immediate-release products is recommended in those who meet the following criteria:

1. **Acromegaly.**

   Initial Therapy: Approve for 1 year if the patient meets the following criteria (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.

   Continuation of Therapy: The patient meets initial criteria AND responded to therapy.

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

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

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

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Octreotide immediate-release products has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Bynfezia Pen™ injection [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries; February 2020.
2. Sandostatin® injection [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals; June 2020.
3. Octreotide injection [prescribing information]. North Wales, PA: Teva Parenteral Medicines; May 2019.
4. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 5.2020 – April 15, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 3, 2021.
5. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 1.2021 – April 14, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 3, 2021.
6. The NCCN Thymomas and Thymic Carcinomas Clinical Practice Guidelines in Oncology (version 1.2021 – December 4, 2020). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 3, 2021.