# 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:** 07/26/2023

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***INSTRUCTIONS FOR USE***

*THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.*

## CIGNA NATIONAL FORMULARY COVERAGE:

### 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. NCCN also notes that everolimus and octreotide may be useful for patients with recurrent meningiomas.[4]
- **Neuroendocrine and Adrenal Tumors:** Guidelines (version 2.2022 – December 21, 2022) 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 1.2023 – December 15, 2022) note that in patients with thymoma who have positive octreotide scan or symptoms of carcinoid syndrome, octreotide therapy may be useful.[6]

## POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of octreotide immediate-release products. All approvals are provided for the duration noted below. 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.

**Bynfezia Pen™ (octreotide acetate immediate-release subcutaneous injection – Sun Pharmaceutical [discontinued])**
**Sandostatin® (octreotide acetate immediate-release subcutaneous or intravenous injection – Novartis, generic)**
**is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

### FDA-Approved Indications

1. **Acromegaly.** 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.

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

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

## CONDITIONS NOT COVERED

**Bynfezia Pen™ (octreotide acetate immediate-release subcutaneous injection – Sun Pharmaceutical [discontinued])**
**Sandostatin® (octreotide acetate immediate-release subcutaneous or intravenous injection – Novartis, generic)**
**is(are) considered experimental, investigational, or unproven for ANY other use(s).**

## REFERENCES


1. Bynfezia Pen™ subcutaneous injection [prescribing information]. Cranbury, NJ: Sun Pharmaceutical; April 2020.
2. Sandostatin® subcutaneous injection [prescribing information]. East Hanover, NJ: Novartis; October 2022.
3. Octreotide subcutaneous injection [prescribing information]. Parsippany, NJ: Teva; February 2023.
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 July 13, 2023.
5. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 2.2022 – December 21, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 13, 2023.

6. The NCCN Thymomas and Thymic Carcinomas Clinical Practice Guidelines in Oncology (version 1.2023 – December 15, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 13, 2023.

## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Annual Revision | No criteria changes. | 06/29/2022 |
| Annual Revision | No criteria changes. | 07/26/2023 |