# PREFERRED SPECIALTY MANAGEMENT POLICY

**POLICY:** Somatostatin Analogs – Octreotide Immediate-Release Products Preferred Specialty Management Policy
- Bynfezia Pen™ (immediate-release octreotide acetate subcutaneous injection – Sun)
- Sandostatin® (immediate-release octreotide acetate subcutaneous or intravenous injection – Novartis, generic)

**REVIEW DATE:** 12/07/2022

## OVERVIEW

Octreotide acetate immediate-release injection products are somatostatin analogs 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.

Table 1 illustrates availability, administration, and storage for each product.

**Table 1. Availability and Storage for Bynfezia Pen, Sandostatin, and Generic Octreotide Injection.[1-3]**

| | Bynfezia Pen | Sandostatin | Octreotide Acetate Immediate-Release Injection | |
|---|---|---|---|---|
| **Availability** | 2.8 mL single-patient-multi-use prefilled pens:<br>• 2,500 mcg/mL<br><br>Dose settings available: 50 mcg, 100 mcg, 150 mcg, and 200 mcg. | 1 mL single-use ampules:<br>• 50 mcg/mL<br>• 100 mcg/mL<br>• 500 mcg/mL | 1 mL single-use vials:<br>• 50 mcg/mL<br>• 100 mcg/mL<br>• 500 mcg/mL | 5 mL multi-use vials:<br>• 200 mcg/mL<br>• 1,000 mcg/mL |
| **Self-Administration** | Proper training is needed for patients and/or caregivers. | | | |
| **Storage** | • Prior to use, store pens in the refrigerator (36° to 46° F).<br>• After first use, store pens at room temperature (68° to 77° F), with excursions permitted to 59° to 86°F.<br>• Discard the pen 28 days after first use. | • For prolonged storage, store in the refrigerator (36° to 46° F).<br>• Stable for 14 days at room temperature (70º to 86º F) if protected from light. | | |
| | | • Discard any unused portion after administration. | | Discard any unused portion 14 days after first use. |

## POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of Preferred Product. For all medications (Preferred and Non-Preferred), the patient is required to meet the standard *Somatostatin Analogs – Octreotide Immediate-Release Products Prior Authorization Policy* criteria. The program directs the patient to try one Preferred Product prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). All approvals are provided for the duration noted below. If the patient meets the standard *Somatostatin Analogs – Octreotide Immediate-Release Products Prior Authorization Policy* criteria, but has not tried a Preferred Product, approval for a Preferred Product will be authorized.

**Automation:** None.

**Preferred Products:** Octreotide acetate immediate-release injection
**Non-Preferred Products:** Bynfezia Pen, Sandostatin

## RECOMMENDED EXCEPTION CRITERIA

| Non-Preferred Product | Exception Criteria |
|---|---|
| Bynfezia Pen | **1.** Approve for 1 year if the patient meets the following (A and B):<br>**A)** Patient meets the standard *Somatostatin Analogs – Octreotide Immediate-Release Products Prior Authorization Policy* criteria; AND<br>**B)** Patient has tried generic octreotide acetate immediate-release injection.<br>**2.** If the patient has met criterion 1A (the standard *Somatostatin Analogs – Octreotide Immediate-Release Products Prior Authorization Policy* criteria), but criterion 1B is not met: approve generic octreotide acetate immediate-release injection. |
| Sandostatin | **1.** Approve for 1 year if the patient meets the following (A and B):<br>**A)** Patient meets the standard *Somatostatin Analogs – Octreotide Immediate-Release Products Prior Authorization Policy* criteria; AND<br>**B)** Patient has tried generic octreotide acetate immediate-release injection.<br>**2.** If the patient has met criterion 1A (the standard *Somatostatin Analogs – Octreotide Immediate-Release Products Prior Authorization Policy* criteria), but criterion 1B is not met: approve generic octreotide acetate immediate-release injection. |

## REFERENCES

1. Bynfezia Pen™ subcutaneous injection [prescribing information]. Cranbury, NJ: Sun Pharmaceutical; February 2020.
2. Sandostatin® subcutaneous or intravenous injection [prescribing information]. East Hanover, NJ: Novartis; October 2022.
3. Octreotide subcutaneous or intravenous injection [prescribing information]. North Wales, PA: Teva; September 2021.