

## PREFERRED SPECIALTY MANAGEMENT POLICY

**POLICY:** Somatostatin Analogs – Octreotide Immediate-Release Products Preferred Specialty Management Policy

- Bynfezia Pen™ (octreotide acetate for subcutaneous injection – Sun Pharmaceutical)
- Octreotide acetate immediate-release injection (Sandostatin®, generic)

**REVIEW DATE:** 12/16/2020

### OVERVIEW

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

- **Acromegaly**, to reduce blood levels of growth hormone and insulin-like growth factor 1 in adult patients 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 adult patients with severe diarrhea and flushing episodes associated with metastatic carcinoid tumors.
- **Vasoactive intestinal peptide (VIP) tumors**, in adult patients 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.**<sup>1-3</sup>

	<b>Bynfezia Pen</b>	<b>Sandostatin</b>	<b>Octreotide Acetate Immediate-Release Injection</b>	
<b>Availability</b>	2.8 mL single-patient-multi-use prefilled pens: <ul style="list-style-type: none"> <li>• 2,500 mcg/mL</li> </ul> Dose settings available: 50 mcg, 100 mcg, 150 mcg, and 200 mcg.	1 mL single-use ampules: <ul style="list-style-type: none"> <li>• 50 mcg/mL</li> <li>• 100 mcg/mL</li> <li>• 500 mcg/mL</li> </ul>	1 mL single-use vials: <ul style="list-style-type: none"> <li>• 50 mcg/mL</li> <li>• 100 mcg/mL</li> <li>• 500 mcg/mL</li> </ul>	5 mL multi-use vials: <ul style="list-style-type: none"> <li>• 200 mcg/mL</li> <li>• 1,000 mcg/mL</li> </ul>
<b>Self-Administration</b>	Proper training to patients and/or caregivers on the administration prior to use according to the “Instructions for Use”.	Careful instruction in sterile subcutaneous injection technique should be given to the patients and to other persons who may administer.		
<b>Storage</b>	<ul style="list-style-type: none"> <li>• Prior to use, store pens in the refrigerator (36° to 46° F).</li> <li>• After first use, store pens at room temperature (68° to 77° F), with excursions permitted to 59° to 86° F.</li> <li>• Discard the pen 28 days after first use.</li> </ul>	<ul style="list-style-type: none"> <li>• For prolonged storage, store in the refrigerator (36° to 46° F).</li> <li>• Stable for 14 days at room temperature (70° to 86° F) if protected from light.</li> </ul>		<ul style="list-style-type: none"> <li>• Discard any unused portion after administration.</li> </ul>
				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. 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.

**Automation:** None.

**Preferred Products:** Octreotide acetate immediate-release injection

**Non-Preferred Products:** Bynfezia Pen, Sandostatin

**RECOMMENDED EXCEPTION CRITERIA**

<b>Non-Preferred Product</b>	<b>Exception Criteria</b>
Bynfezia Pen	<b>1.</b> Approve for 1 year if the patient has tried generic octreotide acetate immediate-release injection.
Sandostatin	<b>1.</b> Approve for 1 year if the patient has tried generic octreotide acetate immediate-release injection.

**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.