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: 12/13/2023

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 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: • 2,500 mcg/mL Dose settings available: 50 mcg, 100 mcg, 150 mcg, and 200 mcg.	1 mL single-use ampules: • 50 mcg/mL • 100 mcg/mL • 500 mcg/mL	1 mL single-use vials: • 50 mcg/mL • 100 mcg/mL • 500 mcg/mL	5 mL multi-use vials: • 200 mcg/mL • 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). • After first use, store pens at room temperature (68° to 77° F), with excursions permitted to 59° to 86°F. • Discard the pen 28 days after first use.	• For prolonged storage, store in the refrigerator (36° to 46° F). • 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.

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

Somatostatin Analogs – Octreotide Immediate-Release non-preferred product(s) is(are) covered as medically necessary when the following non-

preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.

NON-PREFERRED PRODUCT EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Bynfezia Pen	**1.** Approve for 1 year if the patient meets the following (A and B): **A)** Patient meets the standard *Somatostatin Analogs – Octreotide Immediate-Release Products Prior Authorization Policy* criteria; AND **B)** Patient has tried generic octreotide acetate immediate-release injection. **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): **A)** Patient meets the standard *Somatostatin Analogs – Octreotide Immediate-Release Products Prior Authorization Policy* criteria; AND **B)** Patient has tried generic octreotide acetate immediate-release injection. **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; April 2020.
2. Sandostatin® subcutaneous or intravenous injection [prescribing information]. East Hanover, NJ: Novartis; November 2023.
3. Octreotide subcutaneous or intravenous injection [prescribing information]. North Wales, PA: Teva; September 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	12/07/2022
Annual Revision	No criteria changes.	12/13/2023