Effective Date **10/15/2023**
Next Review Date **10/15/2024**
Coverage Policy Number **IP0490**

Octreotide IR (Non-Oncology Indications)

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Related Coverage Resources

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.

Overview

This policy supports medical necessity review for Bynfezia Pen™, Sandostatin® (octreotide acetate immediate-release) injection.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Octreotide immediate-release injection is considered medically necessary when ONE of the following is met (1, 2, 3, 4, 5, 6, or 7):

1. **Acromegaly.** Individual meets **ALL** of the following criteria (A, B, and C):
    A. Individual meets **ONE** of the following (i, ii, or iii):
        i. Inadequate response to surgery and/or radiotherapy
        ii. NOT an appropriate candidate for surgery and/or radiotherapy

iii. Experiencing negative effects due to tumor size (for example, optic nerve compression)

B. Individual 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

Pre-treatment (baseline) refers to the IGF-1 level prior to the initiation of any somatostatin analog (for example, Mycapssa [octreotide delayed-release capsules], an octreotide acetate injection product [for example, Bynfezia Pen, Sandostatin {generic}, Sandostatin LAR Depot], Signifor LAR [pasireotide injection], Somatuline Depot [lanreotide injection], dopamine agonist [for example, 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. **Gastroesophageal variceal hemorrhage, acute.**

3. **Diarrhea associated with chemotherapy or radiation.** Individual meets **EITHER** of the following criteria (A or B):
   A. Individual has Grade 1 or 2 diarrhea and has failed an antimotility medication
   B. Individual has Grade 3 or 4 diarrhea

4. **Enterocutaneous fistula.**

5. **Perioperative management of individuals undergoing pancreatic resection (including fistula).**

6. **Thyroid-stimulating hormone (TSH)-secreting pituitary adenoma.** Individual has had incomplete surgical resection.

7. **Secretory diarrhea in acquired immune deficiency syndrome (AIDS).** Individual has inadequate response to antimicrobial or antimotility agents.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Octreotide immediate-release injection is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration:
- Acromegaly: up to 12 months
- Gastroesophageal variceal hemorrhage, acute: one time
- Diarrhea associated with chemotherapy or radiation: one time
- Enterocutaneous fistula: up to 12 months
- Perioperative management of individuals undergoing pancreatic resection (including fistula): one time
- Thyroid-stimulating hormone (TSH)-secreting pituitary adenoma: up to 12 months
- Secretory diarrhea in acquired immune deficiency syndrome (AIDS): up to 12 months

Reauthorization approval duration:
- Acromegaly: up to 12 months
- Gastroesophageal variceal hemorrhage, acute: not applicable for continuation beyond initial approval duration

- Diarrhea associated with chemotherapy or radiation: not applicable for continuation beyond initial approval duration
- Enterocutaneous fistula: up to 12 months
- Perioperative management of individuals undergoing pancreatic resection (including fistula): not applicable for continuation beyond initial approval duration
- Thyroid-stimulating hormone (TSH)-secreting pituitary adenoma: up to 12 months
- Secretory diarrhea in acquired immune deficiency syndrome (AIDS): up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Coding

1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J2354	Injection, octreotide, non-depot form for subcutaneous or intravenous injection, 25 mcg

Background

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]

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.