Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Somatostatin Analogs: Bynfezia (octreotide), Mycapssa (octreotide)

Effective: January 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Bynfezia Pen (octreotide)

- **Acromegaly**
  To reduce blood levels of growth hormone (GH) and insulin like growth factor (IGF-I) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses
- **Carcinoid Tumors**
  Treatment of severe diarrhea and flushing episodes associated with metastatic carcinoid tumors
- **Vasoactive Intestinal Peptide Tumors**
  Treatment of profuse watery diarrhea associated with Vasoactive Intestinal Peptide tumors (VIPomas)-secreting tumors

Mycapssa (octreotide) is a somatostatin analog indicated for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Bynfezia or Mycapssa for Members when **ALL** of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of acromegaly

AND

2. The prescribing physician is an endocrinologist

AND

3. Documentation the Patient has had a failure of or is unable to tolerate a treatment regimen that included generic injectable octreotide or lanreotide

AND

4. Documentation the Patient is not a candidate for surgery and/or radiation, or has had an inadequate response to surgery and/or radiation

Reauthorization Criteria

1. Documented diagnosis of acromegaly

AND

2. The prescribing physician is an endocrinologist

AND

3. Documentation of a reduction in baseline growth hormone and/or insulin-like growth factor serum concentrations

Carcinoid Tumors and Vasoactive Intestinal Peptide Tumors

The plan may authorize coverage of Bynfezia for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of **one (1)** of the following:
    a. Carcinoid tumor
    b. Vasoactive intestinal peptide tumor

Limitations

1. Initial approvals for the treatment of Acromegaly will be limited to 6 months. Reauthorization of the requested agent will be provided in 12-month intervals.
2. Members new to the plan stable on the requested agent for the treatment of Acromegaly should be reviewed against Reauthorization Criteria.
3. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Mycapssa (octreotide) [prescribing information]. Scotland, United Kingdom: MW Encap Ltd; July 2025.
2. Katznelson L, Laws ER, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2014;99:3933-3951.
3. American Association of Clinical Endocrinologists Acromegaly Guidelines Task Force. Medical guidelines f or clinical practice for the diagnosis and treatment of acromegaly – 2011 update. Endocr Pract. 2011;17(suppl 4):1-44.
4. Bynfezia Pen (octreotide acetate) [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries; February 2025.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. July 1, 2023: No changes
2. July 9, 2024: Removed Bynfezia from the Medical Necessity Guideline due to product discontinuation. (eff 8/1/24)
3. July 8, 2025: No changes. (eff 7/8/25).
4. December 9, 2025: Added Bynfezia to the Medical Necessity Guideline due to product reactivation (eff 1/1/26).

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.