Pharmacy Medical Necessity Guidelines: Acromegaly Agents - Bynfezia™ (octreotide), Mycapssa® (octreotide), and Somavert® (pegvisomant)

Effective: November 16, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATION(S)

Bynfezia Pen (octreotide)

- **Acromegaly**
  To reduce blood levels of growth hormone (GH) and insulin like growth factor (IGF-I) 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**
  Treatment of adult patients with severe diarrhea and flushing episodes associated with metastatic carcinoid tumors
- **Vasoactive Intestinal Peptide Tumors**
  Treatment of adult patients with the profuse watery diarrhea associated with Vasoactive Intestinal Peptide-secreting tumors

Mycapssa (octreotide)

- **Acromegaly**
  Long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide

Somavert (pegvisomant) is a growth hormone receptor antagonist indicated for the treatment of:

- **Acromegaly**
  Acromegaly in patients who have had an inadequate response to surgery or radiation therapy, or for whom these therapies are not appropriate

COVERAGE GUIDELINES

Bynfezia (octreotide)

The plan may authorize coverage of Bynfezia (octreotide) for Members when all of the following criteria are met:

Carcinoid tumors, Vasoactive Intestinal Peptide Tumors

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

Acromegaly

Initial Therapy

1. Documented diagnosis of acromegaly

AND

2. The prescribing physician is an endocrinologist

AND

3. Documentation the Member has had a failure of, or is unable to tolerate, a treatment regimen that included generic injectable octreotide or Somatuline Depot (lanreotide)

AND

4. Documentation the Member 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

Mycapssa (octreotide) and Somavert (pegvisomant)

The plan may authorize coverage of Mycapssa (octreotide) or Somavert (pegvisomant) for Members when all of the following criteria are met:

Acromegaly

Initial Therapy

1. Documented diagnosis of acromegaly

AND

2. The prescribing physician is an endocrinologist

AND

3. Documentation the Member has had a failure of, or is unable to tolerate, a treatment regimen that included generic injectable octreotide or Somatuline Depot (lanreotide)

AND

4. Documentation the Member 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

LIMITATIONS

- 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.
- Members new to the plan stable on the requested agent for the treatment of Acromegaly should be reviewed against Reauthorization Criteria.
- Authorizations for the treatment of carcinoid tumors and vasoactive intestinal peptide tumor are authorized for life of plan.

CODES

Medical billing codes may not be used for this medication. This medication must be obtained via the Member's pharmacy benefit.

REFERENCES

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APPROVAL HISTORY

January 2004: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. January 11, 2005: No changes.
2. January 10, 2006: No changes.
3. December 12, 2006: No changes.
4. November 13, 2007: No changes.
5. March 4, 2008: Changed title from Somavert (pegvisomant) to Acromegaly – Injectable Drugs. Added Pharmacy coverage guidelines for Somatuline Depot. Added HCPCS code for Somatuline Depot.
6. March 10, 2009: No changes.
7. January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred)
8. January 12, 2010: No changes.
9. January 11, 2011: No changes.
10. January 10, 2012: No changes.
11. February 14, 2012: Moved Somatuline Depot from Acromegaly – Injectable Drugs Medical Necessity Guidelines to its own policy. Changed title from Acromegaly – Injectable Drugs to Somavert (pegvisomant).
12. February 12, 2013: No changes.
13. February 11, 2014: No changes.
14. February 10, 2015: No changes.
15. January 1, 2016: Administrative change to rebranded template.
16. February 9, 2016: No changes
17. February 14, 2017: No changes.
18. April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
19. February 13, 2018: No changes.
20. February 12, 2019: No changes.
21. June 9, 2020: Effective October 1, 2020, added Reauthorization Criteria to the Medical Necessity Guideline and the following Limitations: "Initial approval will be limited to 6 months. Reauthorization of Somavert (pegvisomant) will be provided in 12-month intervals" and "Members new to the plan stable on Somavert (pegvisomant) should be reviewed against Reauthorization Criteria."
22. November 10, 2020: Updated title of Medical Necessity Guideline from "Somavet® (pegvisomant)" to "Acromegaly Agents: Bynfezia™ (octreotide), Mycapssa® (octreotide), and Somavert® (pegvisomant)." Added Bynfezia and Mycapssa to the Medical Necessity Guideline. Updated coverage criteria to require "Documentation the Member has had a failure of, or is unable to

tolerate, a treatment regimen that included generic injectable octreotide or Somatuline Depot (lanreotide)." now that additional brand formulations are available.

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.