Pharmacy Medical Necessity Guidelines: Acromegaly Agents for Self-administration

Effective: January 1, 2024

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: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617-673-0939	

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

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Mycapssa (octreotide)

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

Octreotide is a samatostatin analog indicated for:

- **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**
  For the symptomatic treatment of patients with metastatic carcinoid tumors where it suppresses or inhibits the severe diarrhea and flushing episodes associated with the disease
- **Vasoactive Intestinal Peptide Tumors**
  For the treatment of the profuse watery diarrhea associated with Vasoactive Intestinal Peptide-secreting tumors

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

Acromegaly

The plan may authorization coverage of octreotide, Mycapssa (octreotide) or Somavert (pegvisomant) 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 Member is not a candidate for surgery and/or radiation, or has had an inadequate response to surgery and/or radiation

AND

4. If the request is for Mycapssa or Somavert, 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)

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

AND

4. If the request is for Mycapssa or Somavert, 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)

Carcinoid tumors, Vasoactive Intestinal Peptide Tumors

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

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

LIMITATIONS

- For acromegaly, initial approval will be limited to six (6) months. Reauthorization of the requested medication will be provided in 12-month intervals.
- For acromegaly, members new to the plan stable on the requested medication should be reviewed against reauthorization criteria.

CODES

None

REFERENCES

1. Mycapssa (octreotide). [prescribing information]. Needham, MA: Chiasma, Inc.; March 2022.
2. Plöckinger U. Medical therapy of acromegaly. *Int J Endocrinol*. 2012; 2012:268957.
3. Sandostatin (octreotide acetate) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2012.
4. Somavert (pegvisomant for injection) [prescribing information]. New York, NY: Pharmacia & Upjohn Co; July 2023.

APPROVAL HISTORY

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

Subsequent endorsement date(s) and changes made:

- December 12, 2023: Removed Bynfezia from the Medical Necessity Guideline due to product discontinuation (eff 1/1/24).

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.