**Pharmacy Medical Necessity Guidelines: Somavert® (pegvisomant)**

*Effective: October 1, 2020*

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Fax Numbers:
- RXUM: 617.673.0988

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
- 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

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

**OVERVIEW**

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATION(S)**

Somavert (pegvisomant) is a growth hormone receptor antagonist indicated for the treatment of acromegaly in patients who have had an inadequate response to surgery or radiation therapy, or for whom these therapies are not appropriate. The goal of treatment is to normalize serum insulin like growth factor (IGF-I) levels.

Acromegaly is a hormonal disorder resulting from the pituitary gland producing excess growth hormone. The cause, in most cases, is pituitary adenomas. Acromegaly usually affects middle-aged adults and can result in serious illness and premature death. Overgrowth of bone and cartilage can lead to arthritis or carpal tunnel syndrome as well. The most serious health consequences of acromegaly are diabetes mellitus, hypertension, and increased risk of cardiovascular disease. Patients are also at increased risk for polyps of the colon that can develop into cancer.

**COVERAGE GUIDELINES**

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

**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 octreotide 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 approval will be limited to 6 months. Reauthorization of Somavert (pegvisomant) will be provided in 12-month intervals.
- Members new to the plan stable on Somavert (pegvisomant) should be reviewed against Reauthorization Criteria.

**CODES**

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

**REFERENCES**


**APPROVAL HISTORY**

January 2004: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
3. December 12, 2006: 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)
12. February 12, 2013: No changes.
15. January 1, 2016: Administrative change to rebranded template.
16. February 9, 2016: No changes.
17. February 14, 2017: No changes.
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."

**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.