|                           | TTER HEALTH®<br>Policy/Guideline |             | <b>*ae</b>        | etna <sup>™</sup> |
|---------------------------|----------------------------------|-------------|-------------------|-------------------|
| Name:                     | Somavert                         |             | Page:             | 1 of 2            |
| Effective Date: 4/21/2025 |                                  |             | Last Review Date: | 3/26/2025         |
| Applies                   | ⊠Florida Kids                    | ⊠New Jersey | ⊠Maryland         | i                 |
| to:                       | ⊠Pennsylvania Kids               | ⊠Virginia   | ⊠Kentucky PRMD    |                   |

#### Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Somavert under the patient's prescription drug benefit.

# **Description:**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

## FDA-Approved Indication

Somavert is 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.

All other indications are considered experimental/investigational and not medically necessary.

## **Applicable Drug List:**

Somavert

#### Policy/Guideline:

### **Documentation:**

Submission of the following information is necessary to initiate the prior authorization review:

- A. For initial approval: Laboratory report indicating high pretreatment insulin-like growth factor-1 (IGF-1) level and chart notes indicating an inadequate or partial response to surgery or radiotherapy or a clinical reason for not having surgery or radiotherapy
- B. For continuation: Laboratory report indicating normal current IGF-1 levels or chart notes indicating that the member's IGF-1 level has decreased or normalized since initiation of therapy

#### **Criteria for Initial Approval:**

Authorization of 12 months may be granted for the treatment of acromegaly when ALL the following criteria are met:

- A. Member has a high pretreatment IGF-1 level for age and/or gender based on the laboratory reference range.
- B. Member had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason why the member has not had surgery or radiotherapy.

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C. The patient is unable to take Octreotide Acetate Injection followed by Sandostatin Long-Acting Release (LAR) for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

# **Continuation of Therapy:**

Authorization of 12 months may be granted for continuation of therapy for acromegaly when the member's IGF-1 level has decreased or normalized since initiation of therapy.

# **Approval Duration and Quantity Restrictions:**

Initial and Renewal Approval: 12 months

#### **Ouantity Level Limit:**

| Qualitarity = 0.1.01 = minut    |                |  |  |  |
|---------------------------------|----------------|--|--|--|
| Medication                      | Standard Limit |  |  |  |
| Somavert (pegvisomant) Inj 10mg | 30 per 30 days |  |  |  |
| Somavert (pegvisomant) Inj 15mg | 30 per 30 days |  |  |  |
| Somavert (pegvisomant) Inj 20mg | 30 per 30 days |  |  |  |
| Somavert (pegvisomant) Inj 25mg | 30 per 30 days |  |  |  |
| Somavert (pegvisomant) Inj 30mg | 30 per 30 days |  |  |  |

#### **References:**

- 1. Somavert [package insert]. New York, NY: Pharmacia & Upjohn Company LLC; July 2023.
- 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 for clinical practice for the diagnosis and treatment of acromegaly 2011 update. Endocr Pract. 2011;17(suppl 4):1-44.