# Pharmacy Policy Bulletin

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| **Title:** | Pegvisomant (Somavert®) |
| **Policy #:** | Rx.01.232 |

***Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.***

***This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.***

***Members are advised to use participating pharmacies in order to receive the highest level of benefits.***

**Intent:**

The intent of this policy is to communicate the medical necessity criteria for **Pegvisomant (Somavert®)** as provided under the member's prescription drug benefit.

**Description:**

Acromegaly is a disease usually caused by a benign tumor on the pituitary gland, causing increased release of growth hormone (GH). Increased release of growth hormone causes an increase in release of insulin-like growth factor I (IGF-I), causing the signs and symptoms of acromegaly. Excess GH and IGF-1 have both somatic and metabolic effects. The somatic effects include stimulation of growth of many tissues, such as skin, connective tissue, cartilage, bone, viscera, and many epithelial tissues. The metabolic effects include nitrogen retention, insulin antagonism, and lipolysis.

Pegvisomant (Somavert®) is an analog of human growth hormone that has been structurally altered to act as a growth hormone antagonist. It blocks the binding of endogenous growth hormone, interfering with growth hormone signal transduction, causing a decreased serum concentration of IGF-I.

Pegvisomant (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. The goal of treatment is to normalize serum insulin-like growth factor-I (IGF-I) levels.

**Policy:**

**INITIAL CRITERIA:** Pegvisomant (Somavert®) is approved when ALL the following are met:

1. Diagnosis of acromegaly; and
2. One of the following:
    a. Inadequate response to surgery or pituitary irradiation; or
    b. Not a candidate for surgical resection or pituitary irradiation; and
3. Inadequate response or inability to tolerate a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses; and
4. Prescribed by or in consultation with an endocrinologist; and
5. Member is 18 years of age or older

Initial authorization duration: 12 months

**REAUTHORIZATION CRITERA:** Pegvisomant (Somavert®) is re-approved when there is documentation of positive clinical response to Somavert® therapy (i.e., reduction or normalization of IGF-1)

Reauthorization duration: 2 years

**Black Box Warning as shown in the drug Prescribing Information:**

N/A

**Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

**BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

**References:**

Katznelson L, Laws ER Jr, Melmed S, et al. Acromegaly: An Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2014;99(11):3933-3951.

Melmed, S. Causes and clinical manifestations of acromegaly. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed October 17, 2022.

Somavert® (pegvisomant) for injection [prescribing information]. New York, NY: Pfizer Inc.; August 2021. Available from: labeling.pfizer.com/ShowLabeling.aspx?id=3213. Accessed October 17, 2022.

**Applicable Drugs:**

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

| Brand Name | Generic Name |
|---|---|
| Somavert® | Pegvisomant |

**Cross References:**

Rx.01.33 Off Label Use

Rx.01.221 Drugs Exceeding Claim Dollar Limit Threshold

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| **Policy Version Number:** | 3.00 |
| **P&T Approval Date:** | September 15, 2022 |
| **Policy Effective Date:** | January 01, 2023 |
| **Next Required Review Date:** | September 15, 2023 |

you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

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