Pharmacy Policy Bulletin: J-1184 Somavert (pegvisomant) – Commercial and Healthcare Reform	
Number: J-1184	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial**: **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Injectable = Yes w/ Prior Authorization **Healthcare Reform**: Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1184-004	**Original Date:** 06/03/2020
Effective Date: 12/20/2024	**Review Date:** 12/04/2024

Drugs Product(s):	• Somavert (pegvisomant)
FDA-Approved Indication(s):	• 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-1 (IGF-1) levels.

Background:	• Somavert is an analog of human growth hormone (GH) that functions as a GH receptor antagonist. It is a highly selective ligand for the GH receptor; after it binds to the receptor, a decreased production of IGF-1 by the liver and other tissues is seen. • Acromegaly is a chronic disorder caused by GH hypersecretion. Hypersecretion of GH leads to excess production of IGF-1, leading to a multisystem disease characterized by somatic overgrowth, multiple comorbidities, premature mortality, and physical disfigurement. • Over 95% of patients with acromegaly harbor a GH-secreting pituitary adenoma arising from somatotroph cells, leading to GH and IGF-1 hypersecretion. • The Endocrine Society recommends transsphenoidal surgery as the primary therapy in most patients. Repeat surgery should be considered in a patient with residual intrasellar disease following initial surgery. Medical therapy using a somatostatin receptor ligand (SRL) is recommended as primary therapy in patients who cannot be cured by surgery, have extensive cavernous sinus invasion, do not have chiasmal compression, or are poor surgical candidates. • Medical therapy is also recommended in persistent disease following surgery. In patients with significant disease (i.e., with moderate-to-severe signs and symptoms of GH excess and without local mass effects), the use of either a SRL or pegvisomant as the initial adjuvant medical therapy is recommended. • Prescribing Considerations: ○ IGF-1 levels are the biomarker of efficacy with Somavert; the dosage should not be based on GH concentrations or signs and symptoms of acromegaly.

	○ Baseline serum liver tests should be obtained prior to initiating therapy with Somavert. If baseline liver test levels are > 3 times the upper limit of normal (ULN), do not treat with Somavert until a comprehensive workup establishes the cause of the patient's liver dysfunction. ○ Patients with acromegaly and diabetes mellitus being treated with insulin and/or oral hypoglycemic agents may require dose reductions of these therapeutic agents after the initiation of treatment with Somavert.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Somavert may be approved when all of the following criteria are met **(A. through E.)**:

A. The member is 18 years of age or older.

B. The member has a diagnosis of acromegaly (ICD-10: E22.0).

C. The member has high pretreatment insulin-like growth factor-1 (IGF-1) based on laboratory reference range.

D. The member meets one (1) of the following criteria **(a. or b.):**

a. The member has had either inadequate or partial response to surgery or radiotherapy.

b. The member is not a candidate for surgery or radiotherapy.

E. The member has experienced therapeutic failure, contraindication, or intolerance to generic octreotide acetate.

II. Reauthorization

When a benefit, reauthorization of Somavert may be approved when the following criterion is met **(A.)**:

A. The member meets one (1) of the following criteria **(1. or 2.):**

1. Decreased IGF-1 from baseline

2. Normalized IGF-1 from baseline

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and Healthcare Reform Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Somavert [package insert]. New York, NY: Pharmacia & Upjohn Co, Division of Pfizer Inc; July 2023.
2. DRUGDEX System (Micromedex 2.0). Greenwood Village, CO: Truven Health Analytics; 2024.
3. Katznelson, L, Laws, Jr, E, et al. Acromegaly: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2014;99(11):3933-3951.
4. Somavert. Available at: https://www.pfizerpro.com/product/somavert/acromegaly/dosing-and-administration. Accessed November 09, 2021.