pegvisomant (Somavert®)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO149

Description

Pegvisomant (Somavert) selectively binds to growth hormone (GH) receptors on cell surfaces, where it blocks the binding of endogenous GH, and thus interferes with signal transduction. Inhibition of GH action results in decreased serum concentrations of insulin-like growth factor-I (IGF-I), as well as other GH-responsive serum proteins, including IGF binding protein-3 (IGFBP-3), and the acid-labile subunit (ALS).

Length of Authorization

- Initial: 12 months
- Renewal: 12 months

Quantity Limits

Product Name	Dosage Form	Indication	Quantity Limit
pegvisomant (Somavert)	10 mg vial	Acromegaly	60 vials/30 days
	15 mg vial		60 vials/30 days
	20 mg vial		30 vials/30 days
	25 mg vial		30 vials/30 days
	30 mg vial		30 vials/30 days

Initial Evaluation

I. Pegvisomant (Somavert) may be considered medically necessary when the following criteria below are met:
   A. Member is 18 years of age or older; **AND**
   B. Medication is prescribed by, or in consultation with, an endocrinologist; **AND**
   C. A diagnosis of **acromegaly** when the following are met:
      1. Documentation of inadequate response to surgery or radiation therapy; **AND**
      2. Treatment with octreotide (Sandostatin), cabergoline, or bromocriptine (Parlodel) has been ineffective, contraindicated, or not tolerated.

II. Pegvisomant (Somavert) is considered investigational when used for all other conditions.

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan; **AND**

II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. Initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
III. Member has exhibited improvement or stability of disease symptoms.

Supporting Evidence

I. Acromegaly is a hormonal disorder that occurs when the pituitary gland produces too much growth hormone (GH). Typically, this is caused by adenomas (benign tumor) on the pituitary gland. Diagnosis typically occurs in middle-aged adults; however, symptoms can appear at any age. Surgical intervention is the preferred treatment.
II. According to the AACE guidelines, medical therapy is pursued in patients with a tumor that cannot be completely removed surgically, have no compressive tumor effects, are poor surgical candidates, or prefer medical management. Goals of therapy include the normalization of biochemical variables, reversal of mass-effects of the tumor, improvement in signs, symptoms, and comorbidities of disease, and the minimization of long-term mortality risk. In most patients, medical therapy is used as adjuvant treatment in the setting of persistent disease despite surgical intervention.
III. AACE guidelines recommend a random IGF-I value (a marker of integrated GH secretion) to be measured for diagnosis and as post-intervention therapeutic monitoring. A serum IGF-I level should be remeasured at 12 weeks; a normal IGF-I value is consistent with surgical remission. If a repeat serum IGF-I value is reduced from baseline, but is still elevated at 12 weeks, an additional repeat testing is done in another 9 to 12 weeks to determine the presence of delayed biochemical normalization, before proceeding with potential surgical re-exploration, medical therapy, or radiation therapy.
IV. Per guidelines, there are three classes of medical therapy: dopamine agonists (e.g. caberfoline, bromocriptine), somatostatin analogues (e.g. octreotide, lanreotide), and a GH-receptor antagonist (e.g. pegvisomant). Dopamine agonists are considered first-line medical therapy as they are relatively inexpensive in comparison to alternative medical therapy options and have simple oral administration.
V. With the administration of pegvisomant (Somavert), serum IGF-I should be measured alone to monitor the dose efficacy. There is no benefit from the measurement of serum GH in conjunction with pegvisomant (Somavert) therapy. GH levels increase when pegvisomant (Somavert) is administered, and the GH levels have no effect on pegvisomant (Somavert) dosing.

Investigational or Not Medically Necessary Uses

I. There is limited to no evidence to support the use of pegvisomant (Somavert) in any other condition.

References

1. Somavert [Prescribing Information]. New York, NY: Pfizer; September 2019.
2. UpToDate, Inc. Treatment of acromegaly. UpToDate [database online]. Waltham, MA. Last updated August 20, 2019 Available at: http://www.uptodate.com/home/index.html.
3. Katznelson L, Atkinson JL, Cook DM, et al. American Association of Clinical Endocrinologists. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of acromegaly--2011 update. Endocr Pract. 2011 Jul-Aug;17(Suppl 4):1-44.

Policy Implementation/Update:

Date Created	January 2006
Date Effective	January 2006
Last Updated	December 2019
Last Reviewed	12/2019

Action and Summary of Changes	**Date**
Addition of renewal criteria. Added age requirement of 18 years or older. Added requirement for agent to be prescribed by or in consultation with an endocrinologist.	12/2019