PRIOR AUTHORIZATION POLICY

POLICY: Somavert Prior Authorization Policy
- Somavert® (pegvisomant subcutaneous injection – Pfizer)

REVIEW DATE: 08/28/2024

OVERVIEW

Somavert, a growth hormone receptor antagonist, is indicated for the treatment of **acromegaly** in patients who have had inadequate response to surgery and/or radiation therapy and/or other medical therapies, or for whom these therapies are not appropriate.[1] The goal of treatment is to normalize serum insulin-like growth factor-1 levels.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Somavert. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Somavert as well as the monitoring required for adverse events and long-term efficacy, approval requires Somavert to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Somavert is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Acromegaly.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient meets ONE of the following (i, ii, or iii):
     - **i.** Patient has had an inadequate response to surgery and/or radiotherapy; OR
     - **ii.** Patient is NOT an appropriate candidate for surgery and/or radiotherapy; OR
     - **iii.** Patient is experiencing negative effects due to tumor size (e.g., optic nerve compression); AND
   - **B)** Patient has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory; AND
     Note: Pre-treatment (baseline) refers to the IGF-1 level prior to the initiation of any somatostatin analog (e.g., Mycapssa [octreotide delayed-release capsules], an octreotide acetate injection product [e.g., Bynfezia Pen, Sandostatin {generics}, Sandostatin LAR Depot], Signifor LAR [pasireotide intramuscular injection], Somatuline Depot [lanreotide subcutaneous injection]), dopamine agonist (e.g., cabergoline, bromocriptine), or Somavert.
   - **C)** The medication is prescribed by or in consultation with an endocrinologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Somavert is not recommended in the following situations:

1. **Treatment of Excess Growth Hormone Associated with McCune-Albright Syndrome.** Five patients with growth hormone excess due to McCune-Albright Syndrome were treated with 20 mg of Somavert daily for 12 weeks in a randomized, double-blind, placebo-controlled trial at the National Institutes of Health.[2] Somavert reduced IGF-1 and IGF binding protein-3 in these patients but had no effect on fibrous dysplasia.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Somavert® subcutaneous injection [prescribing information]. New York, New York: Pfizer; July 2023.
2. Akintoye SO, Kelly MH, Brillante B, et al. Pegvisomant for the treatment of gsp-mediated growth hormone excess in patients with McCune-Albright Syndrome. *J Clin Endocrinol Metab.* 2006;91:2960-2966.