MEDICAL MUTUAL®

Drug Policy

Policy:	Somavert (pegvisomant for injection)	Annual Review Date: 10/17/2024 Last Revised Date: 10/17/2024

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

POLICY STATEMENT

This policy involves the use of Somavert. Prior authorization is recommended for pharmacy benefit coverage of Somavert. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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, initial approval requires Somavert be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. **Acromegaly**
   Criteria: *Patient must meet the following criteria* (A, B, C, D, E, and F)

   A) The patient is at least 18 years of age; AND
   B) The agent is prescribed by or in consultation with an endocrinologist; AND
   C) The patient has had an inadequate response to or is ineligible for surgery, radiation, or bromocriptine OR is experiencing negative effects due to tumor size (e.g. optic nerve compression); AND
   D) The patient had a baseline IGF-1 level above the upper limit of normal (ULN) for age and gender per the laboratory's standard reference values; AND

Note: Baseline refers to prior to the initiation of any somatostatin analog (e.g. Mycapssa, Bynfezia pen, Sandostatin/Sandostatin LAR, Signifor LAR, Somatuline Depot), dopamine agonist (bromocriptine, cabergoline), or Somavert

E) The patient has tried and failed or has contraindication(s) to the use of generic octreotide subcutaneous injection; AND

F) The patient is NOT currently using Lanreotide or Octreotide.

Initial Approval/ Extended Approval.
A) *Initial Approval: 1 year*
B) *Extended Approval: 1 year*

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Somavert has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Treatment of excess growth hormone associated with McCune-Albright syndrome (MAS).** Five patients with growth hormone excess due to MAS 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. Somavert reduced IGF-1 and IGF binding protein-3 (IGFBP-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.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Somavert® for 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.
3. Pegvisomant. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 25 September 2023. Accessed on 12 October 2023.

4. Laurence Katznelson, Edward R. Laws, Jr, Shlomo Melmed, et al. Acromegaly: An Endocrine Society Clinical Practice Guideline, *The Journal of Clinical Endocrinology & Metabolism*, Volume 99, Issue 11, 1 November 2014, Pages 3933–3951