



Prior Authorization Somavert® (pegvisomant for injection)

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Product Identifier(s)

70760

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National Formulary Medical Necessity

Cigna covers pegvisomant (Somavert®) as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:

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 individuals 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.

FDA Indication(s)

1. **Acromegaly.** Approve for 1 year if the individual meets the following criteria (A, B, and C):
 - A) Individual meets ONE of the following (i, ii, or iii):
 - i. Individual has had an inadequate response to surgery and/or radiotherapy; OR
 - ii. Individual is NOT an appropriate candidate for surgery and/or radiotherapy; OR
 - iii. Individual is experiencing negative effects due to tumor size (e.g., optic nerve compression); AND

- B) Individual has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal (ULN) 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 for injectable suspension], Somatuline® Depot [lanreotide subcutaneous injection]), dopamine agonist (e.g., cabergoline, bromocriptine), or Somavert® (pegvisomant for injection). Reference ranges for IGF-1 vary among laboratories.
- C) The agent is prescribed by or in consultation with an endocrinologist.

Conditions Not Covered

Pegvisomant (Somavert®) is considered experimental, investigational or unproven for ANY other use including the following (this list may not be all inclusive):

1. **Treatment of excess growth hormone associated with McCune-Albright syndrome (MAS).** Five individuals 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.² Somavert reduced IGF-1 and IGF binding protein-3 (IGFBP-3) in these individuals but had no effect on fibrous dysplasia.

Background

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-I levels.

References

1. Somavert® for injection [prescribing information]. New York, New York: Pfizer; August 2019.
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.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	Acromegaly. In the Note section referring to the pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level, Mycapssa® (octreotide delayed-release capsules) and octreotide acetate injection products (Bynfezia Pen™, Sandostatin® [generics]) were added as examples of a somatostatin analog.	08/05/2020

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