



Drug Coverage Policy

Effective Date 11/1/2025

Coverage Policy NumberIP0291

Policy Title.....Somavert

Somavert

- Somavert® (pegvisomant subcutaneous injection – Pfizer)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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.

Coverage Policy

POLICY STATEMENT

Prior Authorization is required for 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.

FDA-Approved Indication

Somavert is considered medically necessary when the following are met:

- 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 Covered

Somavert for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

- 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.

Receipt of sample product does not satisfy any criteria requirements for coverage.

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.

Revision Details

Type of Revision	Summary of Changes	Date
Selected Revision	Acromegaly. Updated from “Documentation of ONE of the following: A.Pre-treatment insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory. B. Growth Hormone (GH) suppression testing demonstrating a lack of growth hormone suppression” to “Documentation the individual 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”	12/15/2024
Annual Review	Removed documentation requirements from Acromegaly criteria.	11/1/2025

The policy effective date is in force until updated or retired.

“Cigna Companies” refers to operating subsidiaries of The Cigna Group. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of The Cigna Group. © 2025 The Cigna Group.