Effective Date.....**12/15/2024**
Coverage Policy Number.....**IP0291**

Pegvisomant

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Related Coverage Resources

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. 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

This policy supports medical necessity review for pegvisomant (**Somavert**®) subcutaneous injection.

Medical Necessity Criteria

Pegvisomant (Somavert) is considered medically necessary when the following are met:

Acromegaly. Individual meets **ALL** of the following criteria:
- A. Documentation of **ONE** of the following:
  - i. Inadequate response to surgery and/or radiotherapy
  - ii. Individual is NOT an appropriate candidate for surgery and/or radiotherapy
  - iii. Experiencing negative effects due to tumor size
- B. Documentation 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
- C. Medication is prescribed by, or in consultation with, an endocrinologist

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

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

Reauthorization Criteria

Continuation of Pegvisomant (Somavert) is considered medically necessary for acromegaly when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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.

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-1 levels.

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	12/15/2024

	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”	

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