



CIGNA PHARMACY COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

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Subject **Pegvisomant (Somavert®)**

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Hyperlink to Related Coverage Policies

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), 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 participant'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 participant's benefit plan document **always supercedes** 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 group 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. Proprietary information of CIGNA. Copyright ©2009 CIGNA

Coverage Policy

CIGNA covers pegvisomant (Somavert®) as medically necessary for a diagnosis of acromegaly when there is an inadequate response to surgery, radiation therapy, and/or other medical therapies, or when these therapies are not appropriate or contraindicated.

General Background

FDA Approved Indications

Somavert is indicated for the treatment of acromegaly in patients who have had an 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 IGF-I levels.

FDA Recommended Dosing

A loading dose of 40 mg of Somavert should be administered subcutaneously under physician supervision. The patient should then be instructed to begin daily subcutaneous injections of 10 mg of Somavert. Serum IGF-I concentrations should be measured every four to six weeks, at which time the dosage of Somavert should be adjusted in 5-mg increments if IGF-I levels are still elevated (or 5-mg decrements if IGF-I levels have decreased below the normal range). While the goals of therapy are to achieve (and then maintain) serum IGF-I concentrations within the age-adjusted normal range and to alleviate the signs and symptoms of acromegaly, titration of dosing should be based on IGF-I levels. It is unknown whether patients who remain

symptomatic while achieving normalized IGF-I levels would benefit from increased dosing with Somavert. The maximum daily maintenance dose should not exceed 30 mg.

Pegvisomant is a human growth hormone (GH) analog that functions as a selective growth hormone receptor antagonist. Pegvisomant selectively binds to growth hormone (GH) receptors on cell surfaces, where it blocks the binding of endogenous GH, and thus interferes with GH signal transduction. Inhibition of GH action results in decreased serum concentrations of insulin-like growth factor-I (IGF-I), as well as other GH-responsive proteins, including IGF binding protein-3 (IGFBP-3), and the acid-labile subunit (ALS). Pegvisomant is indicated for the treatment of acromegaly in patients who have had an 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 IGF-I levels.

The mean extent of absorption of a 20 mg subcutaneous dose is 57%, relative to a 10 mg intravenous dose. Peak concentrations occur 33–77 hours after subcutaneous dosing. Mean volume of distribution is seven liters (L). Clearance is reduced following multiple doses compared to a single dose. Clearance increases with body weight. The half-life is approximately six days following single or multiple doses.

A total of 112 patients with acromegaly previously treated with surgery, radiation therapy, and/or medical therapies participated in a 12-week, randomized, double-blind, multicenter study comparing placebo and pegvisomant. Following withdrawal from previous medical therapy, the 80 patients randomized to treatment with pegvisomant received a subcutaneous (SC) loading dose, followed by 10, 15, or 20 mg/day SC.

Diagnosis was established based on signs and symptoms at presentation, evidence of a pituitary adenoma, and high serum IGF-I concentrations. The mean IGF-I serum concentration declined from baseline by 4% in the placebo group, 26.7% in the 10 mg group, 50.1% in the 15 mg group, and 62.5% in the 20 mg group ($p < 0.001$ for each pegvisomant group vs. placebo). Ring size at Week 12 was smaller in the groups treated with 15 or 20 mg of pegvisomant, compared with placebo. The mean total score for signs and symptoms at week 12 was lower in each of the groups treated with pegvisomant, compared to the group treated with placebo.

Patients on opioids required higher doses of pegvisomant for IGF-I suppression compared with patients not receiving opioids. Patients with diabetes treated with insulin or oral antidiabetic agents may require dosage reductions of these agents after initiation of pegvisomant therapy.

The most common adverse reactions include injection site reactions, pain, diarrhea, and nausea. Injection site reactions have been characterized as mild, self-limited erythematous reactions not requiring treatment. Elevations in serum alanine aminotransferase (ALT) and aspartate aminotransferase (AST) have been reported in some patients.

Coding/Billing Information

Note: This section is not in use.

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