I. Medication Description

Acromegaly is usually caused by a somatotroph (growth hormone-secreting) adenoma of the pituitary gland. Pegvisomant (Somavert®) is a genetically engineered analogue, with attachment of polymers to prolong drug activity, of human growth hormone that functions as a growth hormone receptor antagonist. Rather than inhibiting growth hormone secretion from the tumor, as do current medical treatments for acromegaly (e.g., dopamine-agonists and somatostatin analogues), pegvisomant blocks the action of growth hormone at the tissue level, thus interfering with growth hormone signal transduction. It 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 insulin-like growth factor-I (IGF-I) levels. As serum IGF-I levels return to normal, patients should experience a decrease in the physical signs and symptoms of acromegaly, including soft-tissue swelling, arthralgia, excessive perspiration, and fatigue.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage for Somavert® is provided when the following criteria are met:

- Somavert® is prescribed by, or in consultation with, an endocrinologist AND
- Patient has a confirmed diagnosis of acromegaly, defined by
  - Elevated serum IGF-1 for patient’s age and gender, (including laboratory reference range) AND
  - Elevated growth hormone level nadir of > 1 ng/ml during oral glucose tolerance test AND
- Patient had an inadequate response to surgery and/or radiation therapy and/or other medical therapies (lanreotide, octreotide, or cabergoline) – unless these therapies are not appropriate (patient has unacceptable surgical risk, refuses surgery, or has adenoma(s) that are unlikely to be cured surgically) AND
- Liver enzymes have been assessed prior to starting therapy and recommendation to treat aligns with Somavert’s® prescribing information regarding initiation of therapy based on liver function test results
- Combination therapy with a somatostatin analog (octreotide, lanreotide) will only be covered if Somavert® (pegvisomant) alone is unsuccessful in controlling IGF-1 levels.
IV. **Quantity Limitations**

Covered at up to 900mg each month.

V. **Coverage Duration**

Coverage is provided for 12 months and may be renewed.

VI. **Coverage Renewal Criteria**

Coverage can be renewed based upon the following criteria:

- Patient displays improvement in disease symptoms or stabilization of disease state **AND**
- Patient’s liver enzymes have been assessed and recommendation to continue treatment aligns with Somavert’s® prescribing information for continuation of treatment based on results of liver tests **AND**
- Absence of unacceptable toxicity from the drug

VII. **Billing/Coding Information**

- Available as 10mg, 15mg, 20mg, 25mg, and 30mg vials
- Pertinent diagnosis: acromegaly and gigantism- E22.0

VIII. **Summary of Policy Changes**

- 3/1/11: Changes in maximum billable quantity to reflect maximum daily dosing, addition of Warnings/Precautions section
- 6/15/12: no changes
- 3/15/13: Removal of precautions from warning sections; Policy now pertains to Medicaid/Family Health Plus population
- 3/15/14: no policy changes
- 2/23/15: quantity limits based on max daily dosing implemented
- 3/15/15: no policy changes
- 6/15/15: no policy changes
- 7/1/15: formulary distinctions made
- 6/15/16: no policy changes
- 4/5/17: no policy changes

IX. **References**

1. UpToDate Online, retrieved 1/2017.

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

Drug therapy initiated with samples will not be considered as meeting medical necessity for coverage for non-preferred or prior authorized medications.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary agent will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.