

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Pegvisomant (Somavert)

Initiation (new start) criteria: Non-formulary **pegvisomant (Somavert)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by an endocrinologist
 - Diagnosis of acromegaly by:
 - Serum GH level more than 1 ng/mL after a 2-hour oral glucose tolerance test at time of diagnosis **-OR-**
 - Elevated serum insulin growth factor 1 (IGF-1) levels which are above the age and gender adjusted normal range at time of diagnosis
 - Inadequate response to one of the following:
 - Surgery **-OR-**
 - Radiation therapy **-OR-**
 - Dopamine agonist (e.g., bromocriptine, cabergoline) therapy
- OR-**
- Patient is not a candidate for surgery, radiation therapy, dopamine agonist (e.g., bromocriptine, cabergoline) therapy.
 - Inadequate response, intolerance, or contraindication to one of the following somatostatin analogs:
 - Sandostatin (octreotide) or Sandostatin LAR (octreotide) **-OR-**
 - Somatuline Depot (lanreotide)
- OR-**
- Patient is currently on pegvisomant therapy for acromegaly

Continued use criteria (12 months after initiation): Non-formulary **pegvisomant (Somavert)** will continue to be covered for 12 months on the prescription drug benefit when the following criteria are met:

- Documentation of positive clinical response to pegvisomant therapy
- OR-**
- Serum IGF-1 level has decreased from baseline (at time of initial diagnosis) or is within normal limits