UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Somavert

Program	Prior Authorization
Medication	Somavert® (pegvisomant)
Issue Date	7/2016
Pharmacy and Therapeutics Approval Date	7/2017
Effective Date	9/2017

1. Background:

Somavert® (pegvisomant) is a growth hormone receptor antagonist indicated for the treatment of acromegaly in patients who have had an inadequate response to surgery or radiation therapy, or for whom these therapies are not appropriate. The goal of treatment is to normalize serum insulin-like growth factor-I (IGF-I) levels. The American Association of Clinical Endocrinologists recommends pegvisomant in patients for whom surgical treatment, dopaminergic agents, and somatostatin analogues have proved ineffective or for those who are intolerant of somatostatin analogues.

2. Coverage Criteria:

A. Initial Authorization

1. Somavert will be approved based on **one** of the following criteria:

a. **All** of the following:

(1) Diagnosis of acromegaly by **one** of the following:

(a) Serum GH level > 1 ng/mL after a 2 hour oral glucose tolerance test (OGTT) at time of diagnosis
(b) Elevated serum IGF-1 levels (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis

-AND-

(2) **One** of the following:

(a) Inadequate response to **one** of the following:
i. Surgery
ii. Radiation therapy

iii. Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

-OR-

(b) Not a candidate for **any** of the following:
i. Surgery
ii. Radiation therapy
iii. Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

-AND-

(3) Inadequate response, intolerance, or contraindication to **one** of the following somatostatin analogs:

(a) Sandostatin (octreotide) or Sandostatin LAR
(b) Somatuline Depot (lanreotide)

-OR-

b. Patient is currently on Somavert therapy for acromegaly

Authorization will be issued for 12 months.

B. Reauthorization

1. Somavert will be approved based on the following criteria:

a. Documentation of positive clinical response to Somavert therapy

Authorization will be issued for 12 months.

3. References:

1. Somavert [prescribing information]. Pharmacia & Upjohn Co. New York, NY. April 2016.
2. American Association of Clinical Endocrinologist (AACE) medical guidelines for clinical practice for the diagnosis and treatment of acromegaly. Endocrine Practice. 2004; 10(3): 213-225.
3. Melmed S, Barkan A, Molitch M, et al. Guidelines for Acromegaly Management: An Update. J Clin Endocrinol Metab. May 2009, 94 (5):1509-1517.
4. Katznelson L, Atkinson JL, Cook DM, et al.; American Association of Clinical Endocrinologists. American Association of Clinical Endocrinologists

medical guidelines for clinical practice for the diagnosis and treatment of acromegaly--2011 update. Endocr Pract. 2011 Jul-Aug;17Suppl 4:1-44.

5. Katznelson L, Laws ER Jr, Melmed S, et al. Acromegaly: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. Nov 2014;99(11):3933-3951.

Program	Prior Authorization - Somavert (pegvisomant)
Change Control	
7/2016	New Program
7/2017	Annual review. No changes to the program.