Aetna Better Health®

Pharmacy Prior Authorization
Growth Hormone Antagonists- Clinical Guidelines

Somavert® (pegvisomant)

Indications:
Somavert is 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.

Authorization Guidelines:
May be authorized when the following criteria are met:
- Diagnosis of acromegaly
- Patient is 18 years of age or older
- Prescribed by, or in consultation with an endocrinologist
- Patient has persistent disease following pituitary surgery, or surgical resection is not an option as evidenced by one of the following:
    - Majority of tumor cannot be resected
    - Patient is a poor surgical candidate based on comorbidities
    - Patient prefers medical treatment over surgery, or refuses surgery
- Baseline IGF-1 is ≥2x ULN for age OR IGF-1 remains elevated despite a 6 month trial of maximally tolerated dose of cabergoline (unless patient cannot tolerate cabergoline or has a contraindication)
- Trial and failure of, or intolerance/contraindication to Sandostatin LAR
- Patient has baseline LFT's that are <3x ULN

Initial Approval:
- 6 months

Renewal:
- Indefinite
- Clinical documentation required:
    - Response to therapy (decreased or normalized IGF-1 levels)
    - LFT's

Additional Information:

1. **Recommendations for initiating Somavert based on baseline LFT's:**

Baseline LT Levels	Recommendations
Normal	o May treat with SOMAVERT. o Monitor LTs at monthly intervals during the first 6 months of treatment, quarterly for the next 6 months and then bi-

Pharmacy Prior Authorization
Growth Hormone Antagonists- Clinical Guidelines

Baseline LT Levels	Recommendations
	annually for the next year.
Elevated, but less than or equal to 3 times ULN	May treat with SOMAVERT; however, monitor LTs monthly for at least one year after initiation of therapy and then bi-annually for the next year.
Greater than 3 times ULN	o Do not treat with SOMAVERT until a comprehensive workup establishes the cause of the patient's liver dysfunction. o Determine if cholelithiasis or choledocholithiasis is present, particularly in patients with a history of prior therapy with somatostatin analogs. o Based on the workup, consider initiation of therapy with SOMAVERT. o If the decision is to treat, LTs and clinical symptoms should be monitored very closely.

2. Clinical recommendations based on LFT's during treatment with Somavert:

LT Levels and Clinical Signs/Symptoms	Recommendations
Greater than or equal to 3 but less than 5 times ULN (without signs/symptoms of hepatitis or other liver injury, or increase in serum TBIL)	o May continue therapy with SOMAVERT. However, monitor LTs weekly to determine if further increases occur (see below). o Perform a comprehensive hepatic workup to discern if an alternative cause of liver dysfunction is present.
At least 5 times ULN, or transaminase elevations at least 3 times ULN associated with any increase in serum TBIL (with or without signs/symptoms of hepatitis or other liver injury)	o Discontinue SOMAVERT immediately. o Perform a comprehensive hepatic workup, including serial LTs, to determine if and when serum levels return to normal. o If LTs normalize (regardless of whether an alternative cause of the liver dysfunction is discovered), consider cautious re-initiation of therapy with SOMAVERT, with frequent LT monitoring.

Pharmacy Prior Authorization
Growth Hormone Antagonists- Clinical Guidelines

LT Levels and Clinical Signs/Symptoms	Recommendations
Signs or symptoms suggestive of hepatitis or other liver injury (e.g., jaundice, bilirubinuria, fatigue, nausea, vomiting, right upper quadrant pain, ascites, unexplained edema, easy bruisability)	o Immediately perform a comprehensive hepatic workup. o If liver injury is confirmed, the drug should be discontinued.

3. Normal IGF-1 Levels (by age and gender):

	Females ng/mL	**Males ng/mL**
18 years	109-527	114-493
19 years	104-484	105-441
20 years	98-443	97-398
21-25 years	83-344	84-323
26-30 years	75-275	77-271
31-35 years	71-241	73-244
36-40 years	69-226	68-225
41-45 years	64-210	62-205
46-50 years	59-201	56-194
51-55 years	56-201	53-191
56-60 years	51-194	45-173

Pharmacy Prior Authorization
Growth Hormone Antagonists- Clinical Guidelines

61-65 years	47-191	41-168
66-70 years	46-195	39-168
71-75 years	42-187	36-166
76-80 years	39-184	35-168
80-85 years	37-182	35-179
85-90 years	35-182	33-179

References:

1. Somavert (pegvisomant) [package insert]. NY, NY: Pharmacia & Upjohn Co; Revised September 2014.
2. Melmed S. Treatment of acromegaly. Waltham, MA: UptoDate; Last modified May 22, 2015. http://www.uptodate.com/contents/treatment-of-acromegaly?source=search_result&search=acromegaly&selectedTitle=2%7E84. Accessed August 20, 2015.
3. Katznelson L, Laws ER, Melmed S, et al. Acromegaly: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*, 2014;99(11):3933–3951.