Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Somavert (pegvisomant)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***January 2010***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Somavert (pegvisomant).

Somavert (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 insulin growth factor 1 (IGF-1) levels.

DEFINITIONS

Acromegaly - a disease characterized by hypersecretion of growth hormone (GH) which is most commonly caused by a pituitary somatroph adenoma. Increased circulating levels of GH stimulate increased hepatic production of insulin-like growth factor-1 (IGF-1). Excess IGF-1 causes increased growth of bones and soft-tissues while excess GH can cause co-morbid conditions such as diabetes mellitus, hypertension, and increased cardiovascular risk. Lower circulating GH levels can cause a reversal in the co-morbid diseases and a decrease in IGF-1.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Somavert (pegvisomant), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

I. PLAN DESIGN SUMMARY

Requests for Sandostatin LAR and Signifor LAR are subject to the preferred medical drug list program. This program applies to the acromegaly products specified in this policy. Coverage for a targeted product is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with the targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Acromegaly Products

	Product(s)
Preferred	• Somatuline Depot (lanreotide) • Somavert (pegvisomant)
Non-Preferred	• Sandostatin LAR (octreotide acetate for injectable suspension) • Signifor LAR (pasireotide)

Requests for a non-preferred drug must meet one of the following exception criteria in addition to clinical criteria:

II. EXCEPTION CRITERIA (*Use for Sandostatin LAR/Signifor LAR Requests Only*)

This program applies to members requesting treatment for an indication that is FDA-approved for both of the preferred products.

Coverage for a non-preferred product is provided when ANY of the following criteria is met:

A. Member is currently receiving treatment with the non-preferred product through health insurance, excluding when the non-preferred product is obtained as samples or via manufacturer's patient assistance programs.
B. Member has had a documented inadequate response or intolerable adverse event to ONE of the preferred products.

III. CLINICAL CRITERIA (*Use for ALL Drug Requests*)

Must meet all of the clinical criteria listed under the respective diagnosis:

- Must be prescribed by or in consultation with an endocrinologist
- Must be age 18 years or older
- Must have a confirmed diagnosis of acromegaly to include both of the following baseline (pre-treatment) labs:
    - Elevated serum IGF-1 level for patient's gender and age range. Laboratory reference range must be provided
    - Elevated growth hormone (GH) level defined by a GH level ≥1ng/mL during oral glucose tolerance test (OGTT)
- Must have an inadequate response to surgery or radiation therapy or documentation that these therapies are not appropriate

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months
Reauthorization	Up to 1 year

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Somavert (pegvisomant) Product Information, Pfizer. New York, NY. 6/2008.
2. AACE Medical Guidelines for Clinical Practice for the Diagnosis and Treatment of Acromegaly, May/June.2004. http://www.aace.com/pub/pdf/guidelines/AcromegalyGuidelines2004.pdf.
3. Melmed S, Colao A, Molitch M, et al. Guidelines for Acromegaly Management: An Update. J Clin Endocrinol Metab. 2009;94:1509-1517.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/16, 02/17, 02/18*
Preferred Product Update (effective 4/1/18)	*02/18*