Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/01/2020**
Policy Number: PA.CP.PHAR.389	**Effective Date: 01/2020** **Revision Date: 10/2020**
Policy Name: Pegvisomant (Somavert)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Appendix D updated with 2018 consensus recommendations; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Pegvisomant (Somavert)

Reference Number: PA.CP.PHAR.389
Effective Date: 10.17.18
Last Review Date: 11.20

Revision Log

Description
Pegvisomant (Somavert®) is a growth hormone receptor antagonist.

FDA Approved Indication(s)
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.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness Corporation® that Somavert is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Acromegaly (must meet all)**:**

1. Diagnosis of acromegaly;
2. Prescribed by or in consultation with an endocrinologist;
3. Age ≥ 18 years;
4. Inadequate response to surgical resection or pituitary irradiation (*see Appendix D*), or member is not a candidate for such treatment;
5. Failure of a trial of a somatostatin analog, at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for somatostatin analogs*
6. Dose does not exceed:
   a. Loading dose: 40 mg once;
   b. Maintenance dose: 30 mg per day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

A. Acromegaly (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively therapy (*see Appendix D*);
3. If request is for a dose increase, new dose does not exceed 30 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
IGF: insulin-like growth factor

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
octreotide (Sandostatin®, Sandostatin® LAR Depot)	**Acromegaly** Initial: 50 mcg SC or IV TID Maintenance: 100 to 500 mcg SC or IV TID For patients stable on SC formulation: 20 mg IM intragluteally every 4 weeks for 3 months, then adjust dose based on clinical response	1,500 mcg/day (depot: 40 mg every 4 weeks)
Somatuline® Depot (lanreotide)	**Acromegaly** 90 mg SC once every 4 weeks for 3 months, then adjust dose based on clinical response	120 mg once every 4 weeks
Signifor® LAR (pasireotide)	**Acromegaly** 40 mg to 60 mg IM every 4 weeks	60 mg once every 4 weeks

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: General Information

- Eleventh Acromegaly Consensus Conference: Key recommendations (*Melmed 2018*):
  - Patients be treated at pituitary tumour centres of excellence, where possible, to receive the best and most cost-effective care.
  - Surgical resection of the pituitary adenoma by an experienced neurosurgeon is recommended where possible and represents the best opportunity for cure.
  - Medical therapy is recommended for patients with persistent disease despite surgical resection of the adenoma as well as patients in whom surgery is not appropriate.
  - For patients with persistent disease after surgery, a first-generation long-acting somatostatin receptor ligand (SRL) is recommended as first-line therapy.
  - If clinically relevant residual tumour that is unsuitable for resection is present, patients not adequately controlled on first-generation SRLs could be considered for switching to pasireotide long-acting release.
  - If there is pre-existing clinically relevant impaired glucose metabolism, patients not adequately controlled on first-generation SRLs should be switched to pegvisomant.
- Examples of treatment response to acromegaly therapy (including somatostatin analogs, surgical resection or pituitary irradiation) include improvement from baseline in or normalization of growth hormone (GH) and/or age- and sex-adjusted insulin-like growth factor (IGF-1) serum concentrations, or tumor mass control.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Acromegaly	Loading Dose: 40 mg SC under physician supervision Maintenance: 10 to 30 mg SC QD	Maintenance: 30 mg/day

VI. Product Availability

Single-use vial for reconstitution: 10 mg, 15 mg, 20 mg, 25 mg, 30 mg

VII. References

1. Somavert Prescribing Information. New York, NY: Pfizer Pharmacia & Upjohn Co; August 2019. Available at http://labeling.pfizer.com/ShowLabeling.aspx?id=3213. Accessed on July 27, 2020.
2. Melmed S, Bronstein MD, Chanson P. A Consensus Statement on acromegaly therapeutic outcomes. Nat Rev Endocrinol. 2018 Sep;14(9):552-561. doi: 10.1038/s41574-018-0058-5.
3. Katznelson L, Laws Jr. ER, Melmed S, et al. Acromegaly: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2014;99:3933-3951.
4. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed July 27, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10/18	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/30/19	
4Q 2020 annual review: appendix D updated with 2018 consensus recommendations; age limit added; references reviewed and updated.	08/20	11/20