Clinical Policy: Pegvisomant (Somavert)

Reference Number: PA.CP.PHAR.389
Effective Date: 10/2018
Last Review Date: 10/2023

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. The goal of treatment is to normalize serum insulin-like growth factor-I (IGF-I) levels.

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 PA Health & Wellness ® that Somavert is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of acromegaly as evidenced by one of the following (a or b):
   a. Pre-treatment IGF-I level above the upper limit of normal based on age and gender for the reporting laboratory;
   b. Serum growth hormone (GH) level ≥ 1 µg/mL after a 2-hour oral glucose tolerance test;
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 (*see Appendix B*);
   **Prior authorization may be required for somatostatin analogs*
6. Dose does not exceed the following:
   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 PA Health & 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 PA Health & 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
GH: growth hormone
IGF: insulin-like growth factor
SRL: somatostatin receptor ligand

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® [SC, IV], Sandostatin® LAR Depot [IM]	**Acromegaly** Initial: 50 mcg SC or IV TID Maintenance: 100 to 500 mcg SC or IV TID For patients stable on SC formulation: patients can switch to 20 mg IM intragluteally every 4 weeks for 3 months, then adjust dose based on clinical response	1,500 mcg/day (SC, IV) 40 mg every 4 weeks (IM)
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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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
- Recommendations from the 13th Acromegaly Consensus Conference (*Guistina 2020*) include:
  - Somatostatin receptor ligands (SRLs) such as octreotide LAR and lanreotide are used as first-line medical therapy due to their favorable risk/benefit profiles.
  - Pegvisomant is generally used as second-line therapy in patients who do not achieve biochemical control with maximal doses of SRL therapy.
- Examples of treatment response to acromegaly therapy (including somatostatin analogs, surgical resection or pituitary irradiation) include improvement from baseline in or normalization of GH and/or age- and sex-adjusted IGF-I serum concentrations, or tumor mass control.

V. Dosage and Administration

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

VI. Product Availability
Single-use vials with powder 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; July 2023. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/021106s074lbl.pdf. Accessed on August 3, 2023..
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. Availble at: https://www.nature.com/articles/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 August 3, 2023..

5. Fleseriu M, Biller BMK, Freda PU, et al. A Pituitary Society update to acromegaly management guidelines. Pituitary. 2021; 24: 1-13.
6. Guistina A, Barkhoudarian G, Beckers A, et al. Multidisciplinary management of acromegaly: A consensus. Rev Endocr Metab Disord. 2020; 21(4): 667-678.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10/2018	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/2019	
4Q 2020 annual review: appendix D updated with 2018 consensus recommendations; age limit added; references reviewed and updated.	08/2020	
4Q 2021 annual review: no significant changes; references reviewed and updated.	10/2021	
4Q 2022 annual review: added confirmatory diagnostic requirements (IGF-I or GH) per PS/ES practice guidelines; updated Appendix D with 2020 consensus recommendations; references reviewed and updated.	10/2022	
4Q 2023 annual review: no significant changes; references reviewed and updated.	10/2023	