Clinical Policy: Pegvisomant (Somavert)

Reference Number: ERX.SPA.273
Effective Date: 12.01.18
Last Review Date: 11.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 somatostatin analog* (*octreotide and Somatuline® Depot are preferred*) 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 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 ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to 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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 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 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

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:

Indication	Dosing Regimen	Maximum Dose
	Maintenance: 10 to 30 mg SC QD	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; August 2021. Available at http://labeling.pfizer.com/ShowLabeling.aspx?id=3213. Accessed on July 20, 2022.
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 July 20, 2022.
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	08.14.18	11.18
4Q 2019 annual review: no significant changes; references reviewed and updated.	07.26.19	11.19
4Q 2020 annual review: no significant changes; appendix D updated with 2018 consensus recommendations; references reviewed and updated.	08.11.20	11.20
4Q 2021 annual review: no significant changes; references reviewed and updated.	08.12.21	11.21
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.	07.20.22	11.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.