Clinical Policy: Pegvisomant (Somavert)

Reference Number: ERX.SPA.273
Effective Date: 12.01.18
Last Review Date: 11.18 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.

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 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;
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 (*octreotide or Somatuline® Depot is 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:
   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
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 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 (40 mg every 4 weeks for depot)
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

- The therapeutic goal is normalization of age-adjusted serum insulin-like growth factor-I (IGF-I) levels. Pegvisomant interferes with commercially available growth hormone assays; therefore, growth hormone levels should not be used to adjust therapy.
- Patients should be monitored for growth hormone deficiency.
- Patients should have liver function tests at baseline and monthly for the first 6 months, quarterly for the next six months and every 6 months thereafter if normal. Package insert information contains recommendations if test results are abnormal.
- Patients with diabetes should be monitored for hypoglycemia. Adjustments of hypoglycemic agents may be necessary.
- According to the 2014 American Association of Clinical Endocrinologists (AACE) Acromegaly Guidelines, pegvisomant may be added in a patient with inadequate response to a combo therapy may be warranted if patients are partial responders to a somatostatin receptor ligand. However, combination therapy can lead to an increase in liver function tests and should be monitored closely.
- Temporary use while awaiting the results of surgery or radiation therapy is not recommended.
- 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; April 2016. Available at http://labeling.pfizer.com/ShowLabeling.aspx?id=3213. Accessed on August 14, 2018.
2. Melmed S, Colao A, Barkan A, et al. Guidelines for acromegaly management: An update. J Clin Endocrinol Metab; 2009; 94:1509-1517.
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. Neggers SJ, van Aken MO, Janssen JA, et al. Long-term efficacy and safety of combined treatment of somatostatin analogs and pegvisomant in acromegaly. J Clin Endocrinol Metab 2007; 92:4598-4601.
5. Katznelson L, Atkinson JLD, Cook DM, Ezzat SZ, Hamrahian AH, Miller KK. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of acromegaly – 2011 update. Endocrine Practice. 2011;17(Suppl 4).
6. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed August 14, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08.14.18	11.18

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.