

## Clinical Policy: Pegvisomant (Somavert)

Reference Number: ERX.SPA.273

Effective Date: 12.01.18

Last Review Date: 11.21

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<sup>®</sup>) 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.*

*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<sup>™</sup> 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  $\geq$  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 or Somatuline<sup>®</sup> 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

GH: growth hormone

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® [SC, IV], Sandostatin® LAR Depot [IM])	<b>Acromegaly</b> 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)	<b>Acromegaly</b> 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*

- 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 August 12, 2021.
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. Available 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 12, 2021.

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

**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.

This policy is the property of Envolve Pharmacy Solutions. Unauthorized copying, use, and distribution of this Policy or any information contained herein is strictly prohibited. By accessing this policy, you agree to

be bound by the foregoing terms and conditions, in addition to the Site Use Agreement for Health Plans associated with Envolve Pharmacy Solutions.

©2018 Envolve Pharmacy Solutions. All rights reserved. All materials are exclusively owned by Envolve Pharmacy Solutions and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Envolve Pharmacy Solutions. You may not alter or remove any trademark, copyright or other notice contained herein.