

Clinical Policy: Pegvisomant (Somavert)

Reference Number: CP.PHAR.389

Effective Date: 12.01.18

Last Review Date: 11.18

Line of Business: Commercial, HIM, 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.

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 Centene 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 \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 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:

Medicaid/HIM – 6 months

Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Acromegaly (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
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:

Medicaid/HIM – 12 months

Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid 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)	<p>Acromegaly Initial: 50 mcg SC or IV TID Maintenance: 100 to 500 mcg SC or IV TID</p> <p>For patients stable on SC formulation: 20 mg IM intragluteally every 4 weeks for 3 months, then adjust dose based on clinical response</p>	1,500 mcg/day (depot: 40 mg every 4 weeks)

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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

- 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 2011 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 - adapted from previously approved policy CP.CPA.154; specialist requirement added; age requirement added; modified trial and failure to a somatostatin analog; references reviewed and updated.	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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,

contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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 clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the non-formulary policy; HIM.PA.103.

©2016 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation 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 Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene[®] and Centene Corporation[®] are registered trademarks exclusively owned by Centene Corporation.