Clinical Policy: Pegvisomant (Somavert)

Reference Number: CP.PHAR.389
Effective Date: 12.01.18
Last Review Date: 11.21
Line of Business: Commercial, HIM, Medicaid

Coding Implications
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 ≥ 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 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:
   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.PA.154 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.PA.154 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.PA.154 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
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 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	1,500 mcg/day (SC, IV) 40 mg every 4 weeks (IM)

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	months, then adjust dose based on clinical response	
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

- 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. 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 12, 2021.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3590, C9399	Unclassified drugs or biologicals

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
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; modified reference from HIM.PHAR.21 to HIM.PA.154; added coding implications section; 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. 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.