Clinical Policy: Pegvisomant (Somavert)
Reference Number: CP.PHAR.389
Effective Date: 12.01.18
Last Review Date: 11.20
Line of Business: Commercial, HIM, Medicaid

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; *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.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/ Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>octreotide</td>
<td>Acromegaly</td>
<td>1,500 mcg/day (SC, IV)</td>
</tr>
<tr>
<td>(Sandostatin® [SC, IV], Sandostatin® LAR Depot [IM])</td>
<td>Initial: 50 mcg SC or IV TID</td>
<td>40 mg every 4 weeks (IM)</td>
</tr>
<tr>
<td></td>
<td>Maintenance: 100 to 500 mcg SC or IV TID</td>
<td></td>
</tr>
<tr>
<td></td>
<td>For patients stable on SC formulation: 20 mg IM intragluteally every 4 weeks for 3 months, then adjust dose based on clinical response</td>
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</table>
### Drug Name

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<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Somatuline® Depot (lanreotide)</td>
<td><strong>Acromegaly</strong> 90 mg SC once every 4 weeks for 3 months, then adjust dose based on clinical response</td>
<td>120 mg once every 4 weeks</td>
</tr>
<tr>
<td>Signifor® LAR (pasireotide)</td>
<td><strong>Acromegaly</strong> 40 mg to 60 mg IM every 4 weeks</td>
<td>60 mg once every 4 weeks</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acromegaly</td>
<td>Loading Dose: 40 mg SC under physician supervision</td>
<td>Maintenance: 30 mg/day</td>
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<tr>
<td></td>
<td>Maintenance: 10 to 30 mg SC QD</td>
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</tbody>
</table>

### VI. Product Availability

Single-use vial for reconstitution: 10 mg, 15 mg, 20 mg, 25 mg, 30 mg
VII. References

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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</thead>
<tbody>
<tr>
<td>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.</td>
<td>08.14.18</td>
<td>11.18</td>
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<tr>
<td>4Q 2019 annual review: no significant changes; references reviewed and updated.</td>
<td>07.26.19</td>
<td>11.19</td>
</tr>
<tr>
<td>4Q 2020 annual review: no significant changes; appendix D updated with 2018 consensus recommendations; references reviewed and updated.</td>
<td>08.11.20</td>
<td>11.20</td>
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**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.
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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.

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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.

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