Clinical Policy Title:	pegvisomant
Policy Number:	RxA.283
Drug(s) Applied:	Somavert®
Original Policy Date:	02/07/2020
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All lines of business

Background

Pegvisomant (Somavert®) is a growth hormone receptor antagonist. It 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
pegvisomant (Somavert®)	Acromegaly	Loading Dose: 40 mg SC under physician supervision. Maintenance: 10 to 30 mg SC daily. Adjust dosage in 5 mg increments or decrements until serum IGF-I concentrations are maintained within age-adjusted normal range.	Maintenance: 30 mg/day

Dosage Forms

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

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administer by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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 or older;
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 and b):
   a. Loading dose: 40 mg once;
   b. Maintenance dose: 30 mg per day.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Acromegaly (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy (see Appendix D); and
3. If request is for a dose increase, new dose does not exceed 30 mg per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
IGF: insulin-like growth factor
AACE: American Association of Clinical Endocrinologists
GH: growth hormone
SC: subcutaneous
IV: intravenous
IM: intramuscular

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Maximum Dose
octreotide (Sandostatin®, Sandostatin® LAR Depot)	Initial: 50 mcg SC or IV three times a day Maintenance: 100 to 500 mcg SC or IV three times a day 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 (depot: 40 mg every 4 weeks)
lanreotide (Somatuline® Depot)	90 mg SC once every 4 weeks for 3 months, then adjust dose based on clinical response	120 mg once every 4 weeks

Drug Name	Dosing Regimen	Maximum Dose
pasireotide (Signifor® LAR)	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

- Contraindication(s):
  - None.

- Boxed Warning(s):
  - None.

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 somatostatin analog. 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.

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 April 02, 2021.
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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.
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7. Melmed S, Bronstein MD, Chanson P, et al. A Consensus Statement on acromegaly therapeutic outcomes. *Nat Rev Endocrinol*. 2018;14(9):552-561. doi:10.1038/s41574-018-0058-5.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy reviewed: 1. Formatting updated. 2. References updated. 3. Clinical policy title updated. 4. Drug(s) applied updated. 5. Line of Business updated. 6. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..."	06/21/2020	09/14/2020
Policy was reviewed: 1. Route of administration updated to abbreviations. 2. Dosing regimen updated to include dose titration details. 3. Clinical policy section standard verbiage was updated to include "The provision of provider samples…". 4. Continued therapy criteria II.A.1 was rephrased to "Member is currently receiving medication…". 5. Appendix A for abbreviations was updated. 6. Appendix B for therapeutic alternatives standard verbiage updated. 7. References were updated.	04/02/2021	06/10/2021