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| **Clinical Policy Title:** | pegvisomant |
| **Policy Number:** | RxA.283 |
| **Drug(s) Applied:** | Somavert® |
| **Original Policy Date:** | 02/07/2020 |
| **Last Review Date:** | 10/19/2023 |
| **Line of Business Policy Applies to:** | All lines of business (except Medicare) |

## Criteria

**I. Initial Approval Criteria**

**A. Acromegaly** (must meet all):

1. Diagnosis of acromegaly as evidence by one of the following (a or b):
   a. Pre-treatment IGF-I level above the upper limit of normal based on age and gender for the reporting laboratory;
   b. Serum growth hormone (GH) level ≥ 1 µg/mL after a 2-hour oral glucose tolerance test;
2. Prescribed by or in consultation with an endocrinologist;
3. Age ≥ 18 years;
4. Inadequate response to surgical resection or pituitary irradiation, or member is not a candidate for such treatment;
5. Trial and Failure of a somatostatin analog , 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 the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
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

**References**

1. 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). Available at: https://endosuem.org.uy/wp-content/uploads/2016/07/Guias-AACE-2011.pdf. Accessed January 04, 2023.

| Review/Revision History | Review/Revision Date | P&T Approval Date |
|---|---|---|
| Policy established. | 01/2020 | 02/07/2020 |
| Policy reviewed:<br>1. Formatting updated.<br>2. References updated.<br>3. Clinical policy title updated.<br>4. Drug(s) applied updated.<br>5. Line of Business updated.<br>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:<br>1. Route of administration updated to abbreviations.<br>2. Continued therapy criteria II.A.1 was rephrased to "Member is currently receiving medication…".<br>3. References were updated. | 04/02/2021 | 06/10/2021 |
| Policy was reviewed:<br>1. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".<br>2. References were reviewed and updated. | 01/28/2022 | 4/18/2022 |
| Policy was reviewed:<br>1. Initial Approval Criteria, I.A.1: Updated to include new diagnostic criteria<br>A. Pre-treatment IGF-I level above the upper limit of normal based on age and gender for the reporting laboratory;<br>B. Serum growth hormone (GH) level ≥ 1 µg/mL after a 2-hour oral glucose tolerance test;)<br>2. References were reviewed and updated. | 01/04/2023 | 4/13/2023 |
| Policy was reviewed. | 10/19/2023 | 10/19/2023 |