Clinical Policy: Romosozumab-aqqg (Evenity)

Reference Number: CP.PHAR.428
Effective Date: 05.21.19
Last Review Date: 02.20
Line of Business: Commercial, HIM, Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Romosozumab-aqqg (Evenity™) is a sclerostin inhibitor.

FDA Approved Indication(s)
Evenity is indicated:
- Postmenopausal osteoporosis (PMO): For the treatment of osteoporosis in postmenopausal women at high risk for fracture.*

*High risk of fracture is defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

Limitation(s) of use: Limit duration of use to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered.

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 Evenity is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Osteoporosis (must meet all):
      1. Diagnosis of PMO and (a or b):
         a. Member is at very high risk for fracture (i or ii):
            i. BMD T-score at hip or spine ≤ -3.5;
            ii. BMD T-score at hip or spine ≤ -2.5 AND major osteoporotic fracture (i.e., hip, spine, forearm, wrist, humerus);
         b. Member has completed a 3-year trial of bisphosphonate therapy (alendronate is preferred) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced to both IV and PO formulations (see Appendix D);
         *Prior authorization may be required for bisphosphonates
      2. Age ≥ 18 years or documentation of closed epiphyses on x-ray;
      3. Dose does not exceed 210 mg (2 prefilled syringes) per month.

Approval duration: 6 months (limited to 12 months cumulative use lifetime)
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. Osteoporosis (must meet all):
      1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
      2. Member is responding positively to therapy;
      3. If request is for a dose increase, new dose does not exceed 210 mg (2 prefilled syringes) per month.

   Approval duration: 6 months (limited to 12 months cumulative use lifetime)

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 policies – 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
   BMD: bone mineral density
   FDA: Food and Drug Administration
   GIO: glucocorticoid-induced osteoporosis
   PMO: postmenopausal osteoporosis

   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><strong>IV bisphosphonates</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
   | ibandronate (Boniva) | Treatment: PMO  
   See prescribing information for dose. | Varies                  |
   | zoledronic acid (Reclast®) | Treatment/prevention: PMO, GIO  
   Treatment: male osteoporosis  
   Treatment: Paget disease  
   See prescribing information for dose. |                         |

   **Oral bisphosphonates**
   | alendronate (Fosamax®) | Treatment/prevention: PMO  
   Treatment: GIO, male osteoporosis  
   Treatment: Paget disease  
   See prescribing information for dose. | Varies                  |
### CLINICAL POLICY
Romosozumab-aqqg

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<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
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</tr>
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</table>
| Fosamax® Plus D (alendronate / cholecalciferol) | Treatment: PMO, male osteoporosis  
*See prescribing information for dose.* |                                                                                       |
| risedronate (Actonel®, Atelvia®)              | Actonel: Treatment/prevention: PMO, GIO  
Treatment: male osteoporosis  
Treatment: Paget disease  
Atelvia: Treatment: PMO  
*See prescribing information for dose.* |                                                                                       |
| ibandronate (Boniva®)                         | Treatment/prevention: PMO  
*See prescribing information for dose.* |                                                                                       |

*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):
  - Hypocalcemia
  - Known hypersensitivity to Evenity
- Boxed warning(s):
  - Potential risk of myocardial infarction, stroke, cardiovascular death

**Appendix D: IV/PO Bisphosphonates: Examples of Contraindications and Adverse Effects**

<table>
<thead>
<tr>
<th>Bisphosphonates</th>
<th>Oral Formulations</th>
<th>IV Formulations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Contraindications</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypocalcemia</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Increased risk of aspiration</td>
<td>X</td>
<td>-</td>
</tr>
<tr>
<td>Hypersensitivity to product component</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Inability to stand/sit upright for at least 30 minutes</td>
<td>X</td>
<td>-</td>
</tr>
<tr>
<td>Creatinine clearance &lt; 35 mL/min or evidence of acute renal impairment</td>
<td>-</td>
<td>X</td>
</tr>
<tr>
<td>Esophagus abnormalities which delay emptying such as stricture or achalasia</td>
<td>X</td>
<td>-</td>
</tr>
</tbody>
</table>

**Clinically significant warnings or adverse side effects**
- Pregnancy | X | X |
- Eye inflammation | X | X |
- Acute renal failure | X | X |
- Osteonecrosis of the jaw | X | X |
- Atypical femoral shaft fracture | X | X |
- Drug interactions (product-specific) | X | X |
- Severe or incapacitating musculoskeletal pain | X | X |
V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMO</td>
<td>210 mg (2 prefilled syringes) SC once every month</td>
<td>210 mg/month up to 12 months cumulative use</td>
</tr>
</tbody>
</table>

VI. Product Availability
Prefilled syringe: 105 mg/1.17 mL

VII. References

Osteoporosis Diagnosis, Fracture Risk, and Treatment

Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy created</td>
<td>05.21.19</td>
<td>08.19</td>
</tr>
<tr>
<td>1Q 2020 annual review: added HIM line of business and removed HIM disclaimer for HIM NF drugs; very high fracture risk or 3-year bisphosphonate trial added with required contraindication to both PO/IV formulations; specialists removed; age 18 or closed epiphyses added per PI; references reviewed and updated.</td>
<td>11.19.19</td>
<td>02.20</td>
</tr>
</tbody>
</table>
**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.

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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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