Evenity (romosozumab-aqqg) was initially approved by the FDA in 2019 for the treatment of osteoporosis in postmenopausal women at high risk for fracture, or in patients in whom other available osteoporosis therapy has failed or cannot be taken. Evenity is the only sclerostin inhibitor used for osteoporosis.

Evenity (romosozumab-aqqg) will be considered for coverage when the following criteria are met:

### Osteoporosis

For initial authorization:
1. Member is a postmenopausal woman; AND
2. Member has a diagnosis of osteoporosis, as evidenced by one of the following:
   a) Bone mineral density (BMD) T-score –2.5 or below in the lumbar spine, femoral neck, total proximal femur, or 1/3 radius;
   b) Low-trauma spine or hip fracture (regardless of BMD);
   c) Osteopenia (T-score between –1 and –2.5) with a fragility fracture of proximal humerus, pelvis, or distal forearm;
   d) Osteopenia (T-score between –1 and –2.5) with FRAX fracture probability of ≥ 20% for major osteoporotic fracture or ≥ 3% for hip fracture; AND
3. Member meets one of the following:
   a) Member has had an inadequate response to at least 12 months of an oral bisphosphonate (e.g., alendronate, risedronate) or an IV bisphosphonate (e.g., zoledronic acid (Reclast), ibandronate) OR
   b) Member has very high risk for fracture (e.g., having multiple fractures, very low T score (-3.0 or below), T-score -2.5 or below plus fractures, fractures while taking osteoporosis drug, FRAX > 30% for major osteoporosis fracture or 4.5% for hip fracture2,4) AND has had a trial of zoledronic acid; AND
4. Member does not have any of the following:
   a) Uncorrected hypocalcemia
   b) Prior heart attack (myocardial infarction) or stroke within the last year
   c) Concurrent use with a parathyroid hormone analog (e.g., Forteo, Tymlos) or Prolia.
5. Dosage allowed/Quantity limit: 210 mg (as two 105 mg subQ injections) once a month. (2 syringes per 28 days)

If all the above requirements are met, the medication will be approved for 12 months.

For reauthorization:
1. Evenity will not be reauthorized for continued therapy.
CareSource considers Evenity (romosozumab-aqqg) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>08/01/2019</td>
<td>New policy for Evenity created</td>
</tr>
<tr>
<td>07/31/2020</td>
<td>Osteoporosis definition was updated to accurately reflect current guidelines. Removed dental disease and history of hip fracture from excluded list. Added prior attack or stroke to excluded list per black box warning. Removed list of contraindications for oral bisphosphonates. Removed risk factor appendix. Specified length of oral bisphosphonate trial for 12 months. Specified 2nd line trials to be any IV bisphosphonate or Prolia. Added no concurrent use with PTH or Prolia.</td>
</tr>
<tr>
<td>04/26/2022</td>
<td>Transferred to new template, clarified dose and quantity info, added new reference. Removed ibandronate for very high risk. Removed Prolia trial. Corrected very low T score from -3.5 to -3.0.</td>
</tr>
</tbody>
</table>

References:


Effective date: 10/01/2022
Revised date: 4/26/2022