**Evenity® (Romosozumab)**

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**Definition**

Romosozumab is a parenteral humanized IgG2 monoclonal antibody and sclerostin inhibitor indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, which is defined as a history of osteoporotic fracture or multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. Romosozumab has a dual effect of increasing bone formation and, to a lesser extent, decreasing bone resorption.

**Length of Authorization**

Coverage will be provided for 12 months and may NOT be renewed.

**Dosing Limits**

Max Units (per dose and over time) [Medical Benefit]:

- 210 mg every (1) month

**I. INITIAL APPROVAL CRITERIA**

*Evenity may be considered medically necessary if one of the below conditions are met AND use is consistent with the medical necessity criteria that follows:*

**Osteoporosis**

Evenity is medically necessary when ALL of the following criteria are met:

I. Diagnosis of postmenopausal osteoporosis; AND

II. One of the following: 1-7

A. BMD T-score ≤-2.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site); OR
B. History of one of the following resulting from minimal trauma:
   1. Vertebral compression fracture
   2. Fracture of the hip
   3. Fracture of the distal radius
   4. Fracture of the pelvis
   5. Fracture of the proximal humerus; OR
C. Both of the following:
   1. BMD T-score between -1 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1) based on BMD measurements from lumber spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site)
   2. One of the following:
      a. FRAX 10-year fracture probabilities: major osteoporotic fracture at 20% or more
      b. FRAX 10-year fracture probabilities: hip fracture at 3% or more; AND

III. History of failure, contraindication, or intolerance to oral or intravenous bisphosphonate therapy; AND

IV. Patient is not receiving Evenity in combination with any of the following:
   A. Parathyroid hormone analogs (e.g., Forteo, Tymlos)
   B. RANK ligand inhibitors (e.g., Prolia, Xgeva); AND

V. Evenity dosing is in accordance with the United States Food and Drug Administration approved labeling: 210mg once monthly; AND

VI. Authorization is for no more than 12 months.

Limitations/Exclusions
Evenity is not considered medically necessary for when any of the following selection criteria is met:
   1) The patient has had an MI or stroke within the previous year
   2) The patient has uncorrected hypocalcemia

Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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<tbody>
<tr>
<td>Osteoporosis</td>
<td>Administer 210 mg subcutaneously (as two separate subcutaneous injections of 105 mg each) by a health care provider every month for a total of 12* monthly doses.</td>
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Applicable Procedure Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J3111</td>
<td>Effective 10/1/19, Injection, romosozumab-aqqg, 1 mg</td>
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<tr>
<td>C9399</td>
<td>Unclassified drugs or biologicals</td>
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</tbody>
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Applicable NDCs

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<th>Code</th>
<th>Description</th>
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<tr>
<td>55513-0880-xx</td>
<td>Romosozumab-aqqg 105 mg per 1.17 mL Subcutaneous Solution Prefilled Syringe</td>
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</tbody>
</table>

Applicable Diagnosis Codes
ICD-10 | ICD-10 Description
---|---
M80.00XA | Age-related osteoporosis with current pathological fracture
M80.08XS | Age-related osteoporosis without current pathological fracture

Revision History

8/15/19 | Removed J3590, Added New code J3111, effective 10/1/19.

References