Evenity® (Romosozumab)

Last Review Date: September 23, 2019  Number: MG.MM.PH.195

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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 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>
</tr>
<tr>
<td>C9399</td>
<td>Unclassified drugs or biologicals</td>
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</tbody>
</table>

Applicable NDCs

<table>
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<tr>
<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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Applicable Diagnosis Codes
<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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<tbody>
<tr>
<td>M80.00XA - M80.08XS</td>
<td>Age-related osteoporosis with current pathological fracture</td>
</tr>
<tr>
<td>M81.0</td>
<td>Age-related osteoporosis without current pathological fracture</td>
</tr>
</tbody>
</table>

Revision History

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

References