Evenity™ (romosozumab-aqqg)
(Subcutaneous)

Effective date: 10/01/2019
Review Date: 6/1/2020, 5/20/2021
Revision date: 6/1/2020, 5/20/2021
Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:
   - Evenity 105 mg/1.17 mL single-use prefilled syringe: 2 syringes every 1 month

B. Max Units (per dose and over time) [HCPCS Unit]:
   - 210 billable units every month

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

- Patient is at least 18 years of age; AND
- Confirmation patient is receiving calcium and Vitamin D supplementation if dietary intake is inadequate; AND
- Patient must not have hypocalcemia; AND
- Patient has not had a myocardial infarction or stroke within the preceding year (Note: in patients with other cardiovascular disease and/or risk factors, consider whether benefits of therapy outweigh the risks.); AND

**Osteoporosis in Women**†

- Patient must be at a high risk for fracture**; AND
- Patient must be post-menopausal; AND
- Patient has a documented diagnosis of osteoporosis indicated by one or more of the following:
  - Hip/femur DXA (femoral neck or total hip) or lumbar spine T-score ≤-2.5 and/or forearm DXA 33% (one-third) radius; OR
  - T-score ≤-1 or low bone mass and a history of fragility fracture to the hip or spine; OR
o T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥20% or hip fracture ≥3%; AND

- §Documented treatment failure or ineffective response* to a minimum (12) month trial on previous therapy with bisphosphonates (oral or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid; OR
  - Patient has a documented contraindication* or intolerance to BOTH oral bisphosphonates AND intravenous (IV) bisphosphonates such as alendronate, risedronate, ibandronate, or zoledronic acid; AND

- §Documented treatment failure or ineffective response* to a minimum (12) month trial on previous therapy with RANKL-blocking agents such as denosumab, etc.; OR
  - Patient has a documented contraindication* or intolerance to RANKL-blocking agents such as denosumab, etc.

§ Patients with extremely low BMD (T< -3.5) or a T<-2.5 with a history of fragility fractures are not subject to prior trial and failure requirements with bisphosphonates and/or denosumab.

±Ineffective response is defined as one or more of the following: 5
- Decrease in T-score in comparison with baseline T-score from DXA scan
- Patient has a new fracture while on bisphosphonate therapy

**High risk for fractures include, but are not limited to, one or more of the following: 5
- History of an osteoporotic fracture as an adult
- Parental history of hip fracture
- Low BMI
- Rheumatoid arthritis
- Alcohol intake (3 or more drinks per day)
- Current smoking
- History of oral glucocorticoids ≥5 mg/d of prednisone (or equivalent) for >3 months (ever)

*Examples of contraindications to oral bisphosphonate therapy include the following:
- Documented inability to sit or stand upright for at least 30 minutes
- Documented pre-existing gastrointestinal disorder such as inability to swallow, Barrett’s esophagus, esophageal stricture, dysmotility, or achalasia

*Examples of contraindications to injectable bisphosphonate therapy include the following:
- Documented pre-existing hypocalcemia and disturbances of mineral metabolism
- Documented pre-existing renal insufficiency defined as creatinine clearance < 35 mL/min

*Examples of contraindications to RANKL-blocking therapy include the following:
- Documented pre-existing hypocalcemia and disturbances of mineral metabolism
- Documented hypersensitivity to the active ingredient or its excipients

† FDA Approved Indication(s); ‡ Compendia recommended indication(s)

IV. Renewal Criteria

Coverage may NOT be renewed.
V. 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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*Note: The anabolic effect of Evenity wanes after 12 monthly doses of therapy. Therefore, the duration of Evenity use should be limited to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered.

VI. Billing Code/Availability Information

HCPCS Code:
- J3111 – Injection, romosozumab-aqqg, 1 mg; 1 billable unit = 1 mg

NDC:
- Evenity 105 mg/1.17 mL single-use prefilled syringe: 55513-0880-xx

VII. References


**Appendix 1 – Covered 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>
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**Appendix 2 – Centers for Medicare and Medicaid Services (CMS)**

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: [http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx](http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx). Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

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