Evenity™ (romosozumab-aqqg)  
(Subcutaneous)  

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) [Pharmacy Benefit]:  
   - Evenity 105 mg/1.17 mL single-use prefilled syringe: 2 syringes every 1 month  
B. Max Units (per dose and over time) [Medical Benefit]:  
   - 210 billable units every 1 month  

III. Initial Approval Criteria  
Coverage is provided in the following conditions:  

Osteoporosis in Women †  
- Patient must be supplementing with 1,000 mg of calcium and at least 400 IU of vitamin D daily; **AND**  
- Patient is at least 18 years of age; **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**  
- 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 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**
• 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

  o 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

  o 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:
  - 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:
  - 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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<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

Jcode:
- J3590 – Unclassified biologics
- J3111 – Injection, romosozumab-aqqg, 1 mg; 1 billable unit = 1 mg (Effective 10/1/19)
- C9399 – Unclassified drugs or biologicals (applicable to HOPPS only)

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

VII. References


Appendix 1 – Covered Diagnosis Codes

<table>
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<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) and Local Coverage Determinations (LCDs) 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. Additional indications may be covered at the discretion of the health plan.

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

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<td>Noridian Healthcare Solutions, LLC</td>
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<td>Noridian Healthcare Solutions, LLC</td>
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<td>6</td>
<td>MN, WI, IL</td>
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<tr>
<td>8</td>
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<td>Novitas Solutions, Inc.</td>
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