MEDICAL MUTUAL®

Drug Policy

Policy:	**201918-MRx (04-23)**	**Initial Effective Date: 05/20/2019** **Annual Review Date: 04/20/2023** **Last Revised Date: 04/20/2023**
Code(s):	**HCPCS J3111**	
SUBJECT:	**Evenity™ (romosozumab-aqqg)**	

☒Subject to Site of Care

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

Initial and renewal requests for the medication(s) listed in this policy are subject to site of care management. When billed under the medical benefit, administration of the medication will be restricted to a non-hospital facility-based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless the member meets the site of care exception criteria. To view the exception criteria and a list of medications subject to site of care management please click here.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Evenity is recommended in those who meet the following criteria:

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 [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria [1,17]

- 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 † [1,9,10,14,16,17]

- 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 at the 33% (one-third) radius site; **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**
- Patient has one of the following:
  - **§**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**
- Patient has one of the following:
  - **§**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 very high risk for fracture defined as a T-score ≤-3.0, a T-score ≤-2.5 with a history of fragility fractures, or severe or multiple vertebral fractures are not subject to prior trial and failure requirements with bisphosphonates and/or denosumab* [9-11]

±Ineffective response is defined as one or more of the following: [14,16,17]
– 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:** [16,17]

– 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:** [15]
– Documented inability to sit or stand upright for at least 30 minutes – Documented pre-existing esophageal disorders such as achalasia, esophageal stricture, esophageal varices, or Barrett's esophagus – Surgical anastomoses are present in the GI tract after certain types of bariatric surgery (e.g., Roux-en-Y gastric bypass)
***Examples of contraindications to injectable bisphosphonate therapy include the following:** [15]
– 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); **Φ** Orphan Drug

IV. Renewal Criteria [1]

Coverage may NOT be renewed.

V. Dosage/Administration [1]

Indication	Dose
Osteoporosis	210 mg administered subcutaneously (as two separate subcutaneous injections of 105 mg each) by a health care provider every month for a total of 12***** monthly doses.
*******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

1. Evenity [package insert]. Thousand Oaks, CA; Amgen, Inc.; April 2020. Accessed March 2023.
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4. Kanis JA on behalf of the World Health Organization Scientific Group (2007). Assessment of osteoporosis at the primary health care level. Technical Report. World Health Organization Collaborating Center for Metabolic Bone Diseases. University of Sheffield, UK; 2007.
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13. Saag KG, Petersen J, Brandi ML, et al. Romosozumab or Alendronate for Fracture Prevention in Women with Osteoporosis. N Engl J Med. 2017 Oct 12;377(15):1417-1427. doi: 10.1056/NEJMoa1708322.
14. Camacho PM, Petak SM, Binkley N, et al. AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS/AMERICAN COLLEGE OF ENDOCRINOLOGY CLINICAL PRACTICE GUIDELINES FOR THE DIAGNOSIS AND TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS-2020 UPDATE. Endocr Pract. 2020 May;26(Suppl 1):1-46. doi: 10.4158/GL-2020-0524SUPPL.
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16. Management of osteoporosis in postmenopausal women: the 2021 position statement of The North American Menopause Society. Menopause. 2021 Sep 1;28(9):973-997. Doi: 10.1097/GME.0000000000001831.
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Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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FOR MEDICAL BENEFIT COVERAGE REQUESTS:

Prior approval is required for HCPCS Codes J3111

†When J3111 is determined to be Evenity