

Drug Policy

Policy:	201918-MRx (04-23)	Initial Effective Date: 05/20/2019
Code(s):	HCPCS J3111	Annual Review Date: 04/18/2024
SUBJECT:	Evenity™ (romosozumab-aqqg)	Last Revised Date: 04/18/2024

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 month

B. Max Units (per dose and over time) [HCPCS Unit]:

- 210 billable units every month for 12 doses

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}

This document is subject to the disclaimer found at https://provider.medmutual.com/tools_and_resources/Care_Management/MedPolicies/Disclaimer.aspx and is subject to change. Always verify with the most current version at https://provider.medmutual.com/tools_and_resources/Care_Management/MedPolicies/Disclaimer.aspx or https://provider.medmutual.com/TOOLS_and_RESOURCES/Care_Management/ExpressScripts.aspx.

Drug Policy

- 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**
- Will not be used in combination with bisphosphonates, denosumab, or parathyroid hormone analogs/related peptides; **AND**

Treatment of Postmenopausal Women with Osteoporosis †^{1,9,10,14,16,17}

- Patient must be at a high risk for fracture**;
- Patient has a documented diagnosis of osteoporosis indicated by one or more of the following:
 - T-score by DXA of ≤ -2.5 in the lumbar spine, femoral neck, total hip or forearm at the 33% (one-third) radius site; **OR**
 - History of fragility fracture to the hip or spine, regardless of T-score; **OR**
 - T-score by DXA between -1.0 and -2.5 measured at the lumbar spine, femoral neck, total hip, or forearm at the 33% (one-third) radius site; **AND**
 - History of fracture of proximal humerus, pelvis, or distal forearm; **OR**
 - FRAX 10-year probability for major fracture $\geq 20\%$ or hip fracture $\geq 3\%$; **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 denosumab⁹⁻¹¹

±Ineffective response is defined as one or more of the following:^{14,16,17}

This document is subject to the disclaimer found at https://provider.medmutual.com/tools_and_resources/Care_Management/MedPolicies/Disclaimer.aspx and is subject to change. Always verify with the most current version at https://provider.medmutual.com/tools_and_resources/Care_Management/MedPolicies/Disclaimer.aspx or https://provider.medmutual.com/TOOLS_and_RESOURCES/Care_Management/ExpressScripts.aspx.

Drug Policy

<ul style="list-style-type: none"> – Decrease in T-score in comparison with baseline T-score from DXA scan – Patient has a new fracture while on bisphosphonate or <i>RANKL</i>-blocking therapy
**High risk for fractures include, but are not limited to, one or more of the following: ^{16,17}
<ul style="list-style-type: none"> – 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
<ul style="list-style-type: none"> – 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) – Documented pre-existing hypocalcemia – Documented pre-existing renal insufficiency defined as creatinine clearance < 30-35 mL/min
*Examples of contraindications to injectable bisphosphonate therapy include the following: ¹⁵
<ul style="list-style-type: none"> – Documented pre-existing hypocalcemia – Documented pre-existing renal insufficiency defined as creatinine clearance < 30-35 mL/min
*Examples of contraindications to <i>RANKL</i>-blocking therapy include the following: ¹⁹
<ul style="list-style-type: none"> – Documented pre-existing hypocalcemia – Documented hypersensitivity to the active ingredient or its excipients

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

This document is subject to the disclaimer found at https://provider.medmutual.com/tools_and_resources/Care_Management/MedPolicies/Disclaimer.aspx and is subject to change. Always verify with the most current version at https://provider.medmutual.com/tools_and_resources/Care_Management/MedPolicies/Disclaimer.aspx or https://provider.medmutual.com/TOOLS_and_RESOURCES/Care_Management/ExpressScripts.aspx.

Drug Policy

**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 (carton of two): 55513-0880-xx

VII. References

1. Evenity [package insert]. Thousand Oaks, CA; Amgen, Inc.; April 2020. Accessed February 2024.
2. Cosman F, Crittenden DB, Ferrari S, et al. FRAME Study: The Foundation Effect of Building Bone With 1 Year of Romosozumab Leads to Continued Lower Fracture Risk After Transition to Denosumab. *J Bone Miner Res.* 2018 Jul;33(7):1219-1226. doi: 10.1002/jbmr.3427. Epub 2018 May 17.
3. WHO Scientific Group on the Prevention and Management of Osteoporosis. Prevention and management of osteoporosis: report of a WHO scientific group. (WHO technical report series; 921). Geneva, Switzerland: WHO; 2000.
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.
5. National Osteoporosis Foundation. Clinician's Guide to Prevention and Treatment of Osteoporosis. Washington, DC: National Osteoporosis Foundation; 2014.
6. Camacho PM, Petak SM, Binkley N, et al. American Association Of Clinical Endocrinologists And American College Of Endocrinology Clinical Practice Guidelines For The Diagnosis And Treatment Of Postmenopausal Osteoporosis - 2016. *Endocr Pract.* 2016 Sep 2; 22(Suppl 4):1-42.
7. Qaseem A, Forcica MA, McLean RM, Denberg TD; Clinical Guidelines Committee of the American College of Physicians. Treatment of Low Bone Density or Osteoporosis to Prevent Fractures in Men and Women: A Clinical Practice Guideline Update from the American College of Physicians. *Ann Intern Med.* 2017 May 9. doi: 10.7326/M15-1361.
8. Jeremiah MP, Unwin BK, Greenawald MH, et al. Diagnosis and Management of Osteoporosis. *Am Fam Physician.* 2015 Aug 15;92(4):261-8.

Drug Policy

9. Eastell R, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Clinical Practice Guideline. *J Clin Endo Metab*, Vol 104, Iss 5, May 2019, pps 1595–1622, <https://doi.org/10.1210/jc.2019-00221>.
10. Shoback D, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update. *J Clin Endocrinol Metab*. 2020 Mar 1;105(3):dga048. Doi: 10.1210/clinem/dgaa048.
11. Rosen, HN (2023) Overview of the management of osteoporosis in postmenopausal women. In: Rosen CJ, Schmader KE (Eds). *UpToDate*. Last updated: Feb 19, 2024. Accessed February 26, 2024. Available from https://www.uptodate.com/contents/overview-of-the-management-of-osteoporosis-in-postmenopausal-women?search=verview%20of%20the%20management%20of%20osteoporosis%20in%20postmenopausal%20women&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1.
12. Jackson RD, LaCroix AZ, Gass M, Women’s Health Initiative Investigators. Calcium plus vitamin D supplementation and the risk of fractures. *N Engl J Med*. 2006; 354(7):669–683.
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.
15. Rosen HN. (2023). Bisphosphonate therapy for the treatment of osteoporosis. In Rosen CJ, Schmader KE (Eds.), *UpToDate*. Last updated: May 3, 2023. Accessed February 26, 2024. Available from https://www.uptodate.com/contents/bisphosphonate-therapy-for-the-treatment-of-osteoporosis?sectionName=Contraindications%20to%20bisphosphonates&search=postmenopausal%20osteoporosis&topicRef=2064&anchor=H3422893804&source=see_link#H3422893804.
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.
17. LeBoff MS, Greenspan SL, Insogna KL, et al. The clinician's guide to prevention and treatment of osteoporosis. *Osteoporos Int*. 2022 Oct;33(10):2049-2102. doi: 10.1007/s00198-021-05900-y. Epub 2022 Apr 28.
18. Qaseem A, Hicks LA, Etxeandia-Ikobaltzeta I, et al; Clinical Guidelines Committee of the American College of Physicians. Pharmacologic Treatment of Primary Osteoporosis or Low Bone Mass to Prevent Fractures in Adults: A Living Clinical Guideline From the American College of Physicians. *Ann Intern Med*. [Epub 3 January 2023]. doi:10.7326/M22-1034.

Drug Policy

19. Hildebrand GK, Kasi A. Denosumab. [Updated 2022 Feb 24]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Accessed March 2024. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK535388/>
20. Humphrey, M.B., Russell, L., Danila, M.I., et al. (2023), 2022 American College of Rheumatology Guideline for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis. *Arthritis Rheumatol*, 75: 2088-2102. <https://doi.org/10.1002/art.42646>

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.

FOR MEDICAL BENEFIT COVERAGE REQUESTS:

Prior approval is required for HCPCS Codes J3111

†When J3111 is determined to be Evenity

Edits and Denials:

Prior approval: Prior approval is required for Evenity (**HCPCS Codes J3111**). Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within the Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within Corporate Medical Policy.

TOPPS: Claims received with **HCPCS Codes J3111** will pend with **Remark Code M3M or M4M** and will be adjudicated in accordance with the Corporate Medical Policy.

Liability: A participating provider will be required to write off charges denied as not medically necessary.

Drug Policy

HCPCS Code(s):	
J3111	Injection, romosozumab-aqqg, 1mg effective 10/1/2019

This document is subject to the disclaimer found at https://provider.medmutual.com/tools_and_resources/Care_Management/MedPolicies/Disclaimer.aspx and is subject to change. Always verify with the most current version at https://provider.medmutual.com/tools_and_resources/Care_Management/MedPolicies/Disclaimer.aspx or https://provider.medmutual.com/TOOLS_and_RESOURCES/Care_Management/ExpressScripts.aspx.