Evenity® (romosozumab-aqqg)
(Subcutaneous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 12 months.
- Renewal: Prior authorization validity may NOT be renewed.

II. Dosing Limits

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]

- 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**; **AND**
- 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 ≥ 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 or *RANKL*-blocking 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) – 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]
– Documented pre-existing hypocalcemia – Documented pre-existing renal insufficiency defined as creatinine clearance < 30-35 mL/min
***Examples of contraindications to *RANKL*-blocking therapy include the following:**[19]

– Documented pre-existing hypocalcemia – Documented hypersensitivity to the active ingredient or its excipients

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

IV. Renewal Criteria [1]

Duration of authorization has not been exceeded *(refer to Section I)*

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 plastic prefilled syringe (carton of two): 55513-0880-xx
- Evenity 105 mg/1.17 mL single-use glass prefilled syringe (carton of two): 55513-0998-xx

VII. References

1. Evenity [package insert]. Thousand Oaks, CA; Amgen Inc.; October 2024. Accessed June 2025.
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, Forciea 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.
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):dgaa048. Doi: 10.1210/clinem/dgaa048.
11. Rosen HN, Lewiecki EM (2025) Overview of the management of low bone mass and osteoporosis in postmenopausal women. In: Rosen CJ, Schmader KE, Rubinow K (Eds). *UpToDate.* Last updated: Mar 6, 2025. Accessed June 10, 2025. 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 (2025). Bisphosphonate therapy for the treatment of osteoporosis. In Rosen CJ, Schmader KE, Rubinow K (Eds.), *UptoDate*. Last updated: Mar 10, 2025. Accessed June 10, 2025. 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.
19. Hildebrand GK, Patel P, Kasi A. Denosumab. [Updated 2024 Feb 28]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Accessed June 2025. 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

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
M80.00XA- M80.08XS	Age-related osteoporosis with current pathological fracture
M81.0	Age-related osteoporosis without current pathological fracture

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

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

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC