

Evenity® (romosozumab-aqqg)

(Subcutaneous)

Document Number: IC-0455

Last Review Date: 03/31/2023 Date of Origin: 05/01/2019

Dates Reviewed: 05/2019, 05/2020, 04/2021, 04/2022, 04/2023

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:



- o 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**
- o T-score ≤-1 or low bone mass <u>and</u> 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 \geq 20% or hip fracture \geq 3%; **AND**
- Patient has one of the following:
 - SDocumented 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 \leq -3.0, a T-score \leq -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 $^{9\text{-}11}$

±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 tot 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-		

VI. Billing Code/Availability Information

resorptive agent should be considered.

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.
- 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 (2023) Overview of the management of osteoporosis in postmenopausal women. In: Rosen CJ, Schmader KE (Eds). *UpToDate*. Last updated: Feb 27, 2023. Accessed March 7, 2023. Available from <a href="https://www.uptodate.com/contents/overview-of-the-management-of-osteoporosis-in-postmenopausal-women?search=verview%20of%20the%20management%20of%20osteoporosis%20in%20post menopausal%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. (2022). Bisphosphonate therapy for the treatment of osteoporosis. In Rosen CJ, Schmader KE (Eds.), *UptoDate*. Last updated: July 21, 2022. Accessed March 7, 2023. Available from <a href="https://www.uptodate.com/contents/bisphosphonate-therapy-for-the-treatment-of-osteoporosis?sectionName=Contraindications%20to%20bisphosphonates&search=postmeno-pausal%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.000000000001831.
- 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.

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)

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: https://www.cms.gov/medicare-coverage-database/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

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)		
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, LLC		
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC		
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)		



Medicare Part B Administrative Contractor (MAC) Jurisdictions				
Jurisdiction	Applicable State/US Territory	Contractor		
15	KY, OH	CGS Administrators, LLC		



PreferredOne Community Health Plan Nondiscrimination Notice

PreferredOne Community Health Plan ("PCHP") complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PCHP does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist PreferredOne Community Health Plan PO Box 59052 Minneapolis, MN 55459-0052 Phone: 1.800.940.5049 (TTY: 763.847.4013) Fax: 763.847.4010

customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services 200 Independence Avenue, SW Room 509F, HHH Building Washington, D.C. 20201 1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013). ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013) LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013). XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013). CHÚ Ý: Nếu ban nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho ban. Goi số 1.800.940.5049 (TTY: 763.847.4013). 注意:如果您使用繁體中文,您可以免費獲得語言援助服務。請致電 1.800.940.5049 (TTY: 763.847.4013)。 ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013). ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1.800.940.5049 (TTY: 763.847.4013). ማስታወሻ: የሚናንሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (መስጣት ለተሳናቸው: 763.847.4013). ဟ်သူ၌ဟ်သး– နမ့်ကတိ၊ ကညီ ကျို်အယိ, နမၤန္ရ၊ ကျို်အတါမၤစၤလ၊ တလက်ဘူဉ်လက်စ္၊ နီတမံးဘဉ်သုန္၌လီ၊. ကိႏ 1.800.940.5049 (TTY: 763.847.4013). ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013).។ ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013). ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013). 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1,800,940,5049 (TTY: 763,847,4013), 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa

1.800.940.5049 (TTY: 763.847.4013).

PreferredOne Insurance Company Nondiscrimination Notice

PreferredOne Insurance Company ("PIC") complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PIC does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PIC:

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- · Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- · Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PIC has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Insurance Company
PO Box 59212
Minneapolis, MN 55459-0212
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services 200 Independence Avenue, SW Room 509F, HHH Building Washington, D.C. 20201 1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

Language Assistance Services

```
ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).
ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013)
LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).
XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).
CHÚ Ý: Nếu ban nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho ban. Goi số 1.800.940.5049 (TTY: 763.847.4013).
注意:如果您使用繁體中文,您可以免費獲得語言援助服務。請致電 1.800.940.5049 (TTY: 763.847.4013)。
ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).
ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ
1.800.940.5049 (TTY: 763.847.4013).
ማስታወሻ: የሚናንሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049
(መስጣት ለተሳናቸው: 763.847.4013 ).
ဟ်သူ၌ဟ်သး– နမ့်ကတိ၊ ကညီ ကျို်အယိ, နမၤန္ရ၊ ကျို်အတါမၤစၤလ၊ တလက်ဘူဉ်လက်စ္၊ နီတမံးဘဉ်သုန္၌လီ၊. ကိႏ 1.800.940.5049 (TTY: 763.847.4013).
ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY:
ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013).។
         ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).
ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).
주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1,800,940,5049 (TTY: 763,847,4013), 번으로 전화해 주십시오.
PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa
```

1.800.940.5049 (TTY: 763.847.4013).