

Evenity® (romosozumab-aqqg) (Subcutaneous)

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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 $\geq 20\%$ 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 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 <i>RANKL</i>-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); Ⓢ 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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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.
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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

Nondiscrimination & Language Access Policy

Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity. We do not exclude people or treat them differently because of race, color, national origin, age, disability, sex, sexual orientation, or gender identity.

We will:

Provide 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)

Provide 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 us at the phone number shown on the inside cover of this contract, your id card, or aspirushealthplan.com.

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

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1062
Minneapolis, MN 55440
Phone: 1.866.631.5404 (TTY: 711)
Fax: 763.847.4010
Email: customerservice@aspirushealthplan.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Nondiscrimination Grievance Coordinator 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

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1.866.631.5404 (TTY: 711).

Arabic: تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلی رقم الهاتف 1.866.631.5404 (رقم هاتف الصم والبك : 711)

French: ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelezle 1.866.631.5404 (ATS : 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.866.631.5404 (TTY: 711).

Hindi: _यान द_ : य_द आप िहंदी बोलते ह_ तो आपके िलए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_। 1.866.631.5404 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.866.631.5404 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.866.631.5404 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1.866.631.5404 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.866.631.5404 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (TTY: 711)

Traditional Chinese: 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 1.866.631.5404 (TTY: 711)。

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.866.631.5404 (TTY: 711).

Pennsylvania Dutch: Wann du Deutsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1.866.631.5404 (TTY: 711).

Lao: ໄປດຊາຍ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.866.631.5404 (TTY: 711).