

## Clinical Policy: Romosozumab-aqqg (Evenity)

Reference Number: CP.PHAR.428

Effective Date: 05.21.19

Last Review Date: 08.25

Line of Business: Commercial, HIM, Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

Romosozumab-aqqg (Evenity<sup>®</sup>) is a sclerostin inhibitor.

### FDA Approved Indication(s)

Evenity is indicated for the treatment of osteoporosis in postmenopausal (PMO) women at high risk for fracture\*; or patients who have failed or are intolerant to other available osteoporosis therapy.

*\*High risk of fracture is defined as a history of osteoporotic fracture or multiple risk factors for fracture.*

Limitation(s) of use: Limit duration of use to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Evenity is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Osteoporosis (must meet all):

1. Diagnosis of PMO and one of the following (a or b):
  - a. Member is at very high risk for fracture as evidenced by one of the following (i, ii, or iii):
    - i. Recent osteoporotic fracture (within the past 12 months);
    - ii. Bone mineral density (BMD) T-score at hip or spine  $\leq -3.0$  (*see Appendix E*);
    - iii. BMD T-score at hip or spine  $\leq -2.5$  AND major osteoporotic fracture (i.e., hip, spine, forearm, wrist, humerus) (*see Appendix E*);
  - b. Member has completed a 3-year trial of bisphosphonate therapy\* (*see Appendix B; generic alendronate is preferred*) at up to maximally indicated doses, unless one of the following (i-v):

*\*Prior authorization may be required for bisphosphonates*

    - i. All bisphosphonates are contraindicated;
    - ii. Clinically significant adverse effects are experienced to both IV and PO formulations (*see Appendix D*);
    - iii. Member has experienced a loss of BMD while receiving bisphosphonate therapy;

- iv. Member has experienced a lack of BMD increase after  $\geq 12$  months of bisphosphonate therapy;
- v. Member experienced an osteoporotic fracture or fragility fracture while receiving bisphosphonate therapy;
- 2. Age  $\geq 18$  years or documentation of closed epiphyses on x-ray;
- 3. Member has not received  $\geq 12$  months cumulative romosozumab therapy;
- 4. Dose does not exceed both of the following (a and b):
  - a. 210 mg per month;
  - b. 2 prefilled syringes per month.

**Approval duration:**

**Medicaid/HIM** – 12 months (*limited to 12 months cumulative romosozumab use lifetime*)

**Commercial** – 6 months or to the member’s renewal date, whichever is longer (*limited to 12 months cumulative romosozumab use lifetime*)

**B. Other diagnoses/indications (must meet 1 or 2):**

- 1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
- 2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. Osteoporosis (must meet all):**

- 1. Re-authorization is not permitted. Members must meet the initial approval criteria.

**Approval duration: Not applicable**

**B. Other diagnoses/indications (must meet 1 or 2):**

- 1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or



Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): hypocalcemia; known hypersensitivity to Evenity
- Boxed warning(s): potential risk of myocardial infarction, stroke, and cardiovascular death

*Appendix D: IV/PO Bisphosphonates: Examples of Contraindications and Adverse Effects*

<b>Bisphosphonates</b>	<b>Oral Formulations</b>	<b>IV Formulations</b>
<b><i>Contraindications</i></b>		
Hypocalcemia	X	X
Increased risk of aspiration	X	-
Hypersensitivity to product component	X	X
Inability to stand/sit upright for at least 30 minutes	X	-
Creatinine clearance < 35 mL/min or evidence of acute renal impairment	-	X
Esophagus abnormalities which delay emptying such as stricture or achalasia	X	-
<b><i>Clinically significant warnings or adverse side effects</i></b>		
Pregnancy	X	X
Eye inflammation	X	X
Acute renal failure	X	X
Osteonecrosis of the jaw	X	X
Atypical femoral shaft fracture	X	X
Drug interactions (product-specific)	X	X
Severe or incapacitating musculoskeletal pain	X	X

*Appendix E: General Information*

- Bone Mineral Density (BMD) T-score was established by the World Health Organization (WHO) as the operational definition for post-menopausal osteoporosis. The T-score is the standard deviation of an individual's BMD from the mean value for young normal women. A normal T-score is considered -1.0 or above.
- The 2020 American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines use the T-score to diagnosis postmenopausal women with osteoporosis. When an individual's T-score is -2.5 or below, the individual is considered to have osteoporosis or severe osteoporosis in the presence of a fragility fracture (i.e., a fracture sustained from force similar to a fall from a standing position or less that would not have occurred in healthy bone).

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
PMO	210 mg (2 prefilled syringes) SC once every month	210 mg/month up to 12 months cumulative use

**VI. Product Availability**

Prefilled syringe: 105 mg/1.17 mL

**VII. References**

1. Evenity Prescribing Information. One Amgen Center Drive, Thousand Oaks, CA; Amgen Inc.: April 2024. Available at: <https://www.evenityproliahcp.com/>. Accessed October 22, 2024.
2. Clinical Pharmacology [database online]. Tampa, FL: Elsevier 2023. Available at: [www.clinicalkeys.com/pharmacology](http://www.clinicalkeys.com/pharmacology).
3. *Osteoporosis Diagnosis, Fracture Risk, and Treatment*
3. Shoback D, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: an endocrine society guideline update. *J Clin Endocrinol Metab*; March 2020, 105(3): 587-594.
4. Eastell R, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*; 2019, 104: 1595–1622.
5. Camacho PM, Petak SM, Brinkley 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;26(1):1-46.
6. LeBogg MS, Greenspan SL, Insongna KL, et al. Clinician’s guide to prevention and treatment of osteoporosis. *Osteoporos Int*. 2022 Oct;33(10):2049-2102. doi:10.1007/s00198-021-05900-y. Erratum in: *Osteoporos Int*. 2022 Jul 28.
7. Siris ES, Adler R, Bilezikian J, et al. The clinical diagnosis of osteoporosis: a position statement from the National Bone Health Alliance Working Group. *Osteoporos Int*. 2014; 25:1439–1443. DOI 10.1007/s00198-014-2655-z.
8. Hodsman AB, Bauder DC, Dempster DW, et al. Parathyroid hormone and teriparatide for the treatment of osteoporosis: a review of the evidence and suggested guidelines for its use. *Endocr Rev*. 2005;26(5):688-703. Epub 2005 Mar 15.
9. Qaseem A, Hicks LA, Etcheandia-Ikobaltzeta I, et al. Pharmacologic Treatment of Primary Osteoporosis or Low Bone Mass to Prevent Fractures in Adults: A Living Clinical Guideline From the American College of Physicians (Version 1, Update Alert). *Ann Intern Med*. 2024 Jun; 177(6): eL230113.

**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3111	Injection, romosozumab-aqqg, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2021 annual review: no significant changes; references to HIM.PHAR.21 revised to HIM.PA.154; added coding implications; references reviewed and updated.	10.26.20	02.21
1Q 2022 annual review: updated definition of very high risk for fracture per 2020 AACE/ACE PMO treatment guideline; references reviewed and updated.	09.16.21	02.22
Added option (in addition to contraindications or adverse effects) to bypass bisphosphonate trial if member has experienced a loss of BMD, lack of BMD increase, or has had an osteoporotic fracture or fragility fracture while receiving bisphosphonate therapy.	02.07.22	05.22
Template changes applied to other diagnoses/indications and continued therapy section.	09.23.22	
1Q 2023 annual review: no significant changes; references reviewed and updated.	11.01.22	02.23
1Q 2024 annual review: added criteria to ensure the member has not received $\geq 12$ months cumulative Evenity therapy before approval per PI; clarified failure of “generic” alendronate is preferred; clarified dosage regimen in Appendix B per PI; reference reviewed and updated.	10.23.23	02.24
1Q 2025 annual review: no significant changes; added Appendix E to provide clarity on the interpretation of bone mineral density T-scores; references reviewed and updated.	10.22.24	02.25
Revised initial approval duration to 12 months for Medicaid/HIM; added Commercial approval duration of 6 months or to the member’s renewal date, whichever is longer; revised continuation of therapy to state member must meet the initial approval criteria.	04.14.25	08.25

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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