

Clinical Policy: Romosozumab-aqqg (Evenity)

Reference Number: CP.PHAR.428

Effective Date: 05.21.19

Last Review Date: 05.22

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™) is a sclerostin inhibitor.

FDA Approved Indication(s)

Evenity is indicated:

- **Postmenopausal osteoporosis (PMO):** For the treatment of osteoporosis in postmenopausal women at high risk for fracture.*

**High risk of fracture is defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.*

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® 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 ≤ -3.0 ;
 - iii. BMD T-score at hip or spine ≤ -2.5 AND major osteoporotic fracture (i.e., hip, spine, forearm, wrist, humerus);
 - b. Member has completed a 3-year trial of bisphosphonate therapy (*see Appendix B; alendronate is preferred*) at up to maximally indicated doses, unless one of the following (i-v):
 - 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 ≥ 12 months of bisphosphonate therapy;
 - v. Member experienced an osteoporotic fracture or fragility fracture while receiving bisphosphonate therapy;
- *Prior authorization may be required for bisphosphonates*
- 2. Age ≥ 18 years or documentation of closed epiphyses on x-ray;
 - 3. Dose does not exceed 210 mg (2 prefilled syringes) per month.

Approval duration: 6 months (limited to 12 months cumulative use lifetime)

B. Other diagnoses/indications

- 1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): 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. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
- 2. Member is responding positively to therapy;
- 3. If request is for a dose increase, new dose does not exceed 210 mg (2 prefilled syringes) per month.

Approval duration: 6 months (limited to 12 months cumulative use lifetime)

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BMD: bone mineral density GIO: glucocorticoid-induced osteoporosis
FDA: Food and Drug Administration PMO: postmenopausal osteoporosis

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
<i>IV bisphosphonates</i>		
ibandronate (Boniva)	Treatment: PMO <i>See prescribing information for dose.</i>	Varies
zoledronic acid (Reclast [®])	Treatment/prevention: PMO, GIO Treatment: male osteoporosis	

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Treatment: Paget disease <i>See prescribing information for dose.</i>	
Oral bisphosphonates		
alendronate (Fosamax [®])	Treatment/prevention: PMO Treatment: GIO, male osteoporosis Treatment: Paget disease <i>See prescribing information for dose.</i>	Varies
Fosamax [®] Plus D (alendronate / cholecalciferol)	Treatment: PMO, male osteoporosis <i>See prescribing information for dose.</i>	
risedronate (Actonel [®] , Atelvia [®])	Actonel: Treatment/prevention: PMO, GIO Treatment: male osteoporosis Treatment: Paget disease Atelvia: Treatment: PMO <i>See prescribing information for dose.</i>	
ibandronate (Boniva [®])	Treatment/prevention: PMO <i>See prescribing information for dose.</i>	

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) 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, cardiovascular death

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

Bisphosphonates	Oral Formulations	IV Formulations
Contraindications		
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	-

Bisphosphonates	Oral Formulations	IV Formulations
<i>Clinically significant warnings or adverse side effects</i>		
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

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: April 2020. Available at: <https://www.evenityhcp.com>. Accessed September 16, 2021.
 2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. Available at: <http://www.clinicalpharmacology-ip.com/>.
- 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. National Osteoporosis Foundation Clinician’s Guide to Prevention and Treatment of Osteoporosis. *Osteoporosis International*. 2014. Available at: <https://cdn.nof.org/wp-content/uploads/2016/01/995.pdf>. Accessed September 16, 2021.
 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.

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
Policy created	05.21.19	08.19
1Q 2020 annual review: added HIM line of business and removed HIM disclaimer for HIM NF drugs; very high fracture risk or 3-year bisphosphonate trial added with required contraindication to both PO/IV formulations; specialists removed; age 18 or closed epiphyses added per PI; references reviewed and updated.	11.19.19	02.20
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

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.

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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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