Draft Revision Policy: Do Not Implement

Romosozumab-aqqg (Evenity®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Evenity is indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

Limitations 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.

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- Chart notes or medical record documentation indicating a history of fragility fractures, T-score, and Fracture Risk Assessment Tool (FRAX) fracture probability as applicable to the coverage criteria section.
- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

COVERAGE CRITERIA

Postmenopausal Osteoporosis

Authorization of a total of 12 months may be granted to postmenopausal members with osteoporosis when EITHER of the following criteria is met:

- Member has a history of fragility fractures (e.g., low trauma fracture from force similar to a fall from standing position).
- Member has a pre-treatment T-score ≤ ~~less than or equal to~~ -2.5 OR member has osteopenia (i.e., pre-treatment T-score between -1 and -2.5 ~~greater than -2.5 and less than -1)~~ with a high pre-treatment FRAX ~~fracture~~ probability (see Appendix ~~B~~) and meets any of the following criteria:

- Member has indicators of very high fracture risk (e.g., advanced age, frailty, glucocorticoid use, very low T-scores [≤ ~~less than or equal to~~ -3], or increased fall risk)
- Member has had an inadequate response or intolerance to ~~failed prior treatment with or is intolerant~~ to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], teriparatide [Forteo], a denosumab product [e.g. Prolia and biosimilars ~~Jubbonti, Ospomyv, Stoboclo~~], abaloparatide [Tymlos])
- Member has had an inadequate response or intolerance to previous ~~oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with~~ an oral bisphosphonate therapy ~~(see Appendix A)~~

CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria section and have received less than 12 monthly doses of Evenity.

APPENDIX

~~**Appendix A. Clinical Reasons to Avoid Oral Bisphosphonate Therapy**~~

- ~~Presence of anatomic or functional esophageal abnormalities that might delay transit of the tablet (e.g., achalasia, stricture, or dysmotility)~~
- ~~Active upper gastrointestinal problem (e.g., dysphagia, gastritis, duodenitis, erosive esophagitis, ulcers)~~
- ~~Presence of documented or potential gastrointestinal malabsorption (e.g., gastric bypass procedures, celiac disease, Crohn's disease, infiltrative disorders)~~
- ~~Inability to stand or sit upright for at least 30 to 60 minutes~~
- ~~Inability to take oral bisphosphonate at least 30 to 60 minutes before first food, drink, or medication of the day~~
- ~~Renal insufficiency (creatinine clearance <35 mL/min)~~
- ~~History of intolerance to an oral bisphosphonate~~

~~**Appendix B.**~~ **FRAX Fracture Risk Assessment Tool**

- FRAX© (fracture risk assessment tool) available at: https://fraxplus.org
- High FRAX probability: 10-year major osteoporotic fracture probability ≥ 20% or hip fracture probability ≥ 3%
- FRAX Glucocorticoid correction: If glucocorticoid dose is greater than 7.5 mg (prednisone equivalent) per day, the estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture (including fractures of the spine [clinical], hip, wrist, or humerus) and 1.2 for hip fracture.

- ~~High FRAX fracture 10-year probability: Major osteoporosis-related fracture risk ≥ 20% or hip fracture risk ≥ 3%.~~
- ~~10-year probability; calculation tool available at: https://frax.shef.ac.uk/FRAX/.~~
- ~~The estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture (including fractures of the spine [clinical], hip, wrist, or humerus) and 1.2 for hip fracture if glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day.~~

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-

label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

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2. LeBoff MS, Greenspan SL, Insogna KL, et al. The Clinician's guide to prevention and treatment of osteoporosis. *Osteoporos Int.* 2022;33(10): 2049-2102.
3. 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;26 (Suppl 1):1-46.
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.
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6. Carey, John. What is failure of bisphosphonate therapy for osteoporosis. Cleve Clinic J Med. 2005; 72:1033-1039.
7. FRAX® Fracture Risk Assessment Tool. © Osteoporosis Research Ltd, ~~Centre for Metabolic Bone Diseases, University of Sheffield,~~ UK. Available online: https://fraxplus.org. ~~at: https://frax.shef.ac.uk/FRAX/~~.Accessed September 5, 2025.
8. Ensrud KE, Crandall CJ. Osteoporosis. Ann Intern Med 2024;177(1):ITC1-ITC16.~~167(03):ITC17-ITC32.~~

EFFECTIVE DATE

ID_CHS_2025