Reference number(s)
2921-A

SPECIALTY GUIDELINE MANAGEMENT

EVENITY (romosozumab-aqqg)

POLICY

I. 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 Indication
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.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Supporting chart notes or medical record indicating a history of fragility fractures, T-score, and FRAX fracture probability as applicable to Section III.

III. CRITERIA FOR INITIAL APPROVAL

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

A. Member has a history of fragility fractures
B. Member has a pre-treatment T-score less than or equal to -2.5 OR member has osteopenia (i.e., pre-treatment T-score 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:
    1. 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)
    2. Member has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], teriparatide [Forteo, Bonsity], denosumab [Prolia], abaloparatide [Tymlos])
    3. Member has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate (see Appendix A)

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria AND have received less than 12 monthly doses of Evenity.

V. APPENDICES

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

- High FRAX fracture probability: 10-year major osteoporosis-related fracture risk ≥ 20% or hip fracture risk ≥ 3%.
- 10-year probability; calculation tool available at: https://www.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.

VI. REFERENCES

1. Evenity [package insert]. Thousand Oaks, CA: Amgen; April 2020.
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.
5. Carey, John. What is failure of bisphosphonate therapy for osteoporosis. *Cleve Clinic J Med.* 2005; 72:1033-1039.
6. FRAX® Fracture Risk Assessment Tool. © Centre for Metabolic Bone Diseases, University of Sheffield, UK. Available at: https://www.sheffield.ac.uk/FRAX/. Accessed October 5, 2023.
7. Ensrud KE, Crandall CJ. *Osteoporosis.* Ann Intern Med 2017;167(03):ITC17–ITC32.