Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Evenity under the patient's prescription drug benefit.

Description:

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.

Drug List:

Non-Preferred: Evenity

Policy/Guideline:

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 below:

Postmenopausal osteoporosis treatment
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 is unable to take Tymlos, Prolia, and teriparatide 620mg/2.48mL due to a trial and inadequate treatment response or intolerance, or a contraindication and has a history of fragility fractures
B. Member is unable to take Tymlos, Prolia, and teriparatide 620mg/2.48mL due to a trial and inadequate treatment response or intolerance, or a contraindication and 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
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)

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.

Approval Duration and Quantity Restrictions:

Approval: Initial and Renewal: 12 months

Quantity Level Limit: 2 per 30 days
Reference Formulary for drug specific quantity level limits

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, etc.)
- 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. WHO Fracture Risk Assessment Tool

- High FRAX fracture probability: 10 year major osteoporotic 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.

References:

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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.
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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.