Mass General Brigham
Health Plan

Evenity® (romosozumab-aqqg)
Effective 04/01/2023

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy when obtained through the pharmacy benefit.		
Contact Information	**Medical and Specialty Medications**		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview
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.

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met, and documentation is provided:

<u>Treatment/prevention of osteoporosis</u>
Prescriber provides **medical records** documenting **ALL** of the following:
1. Appropriate diagnosis
2. Bone mineral density (BMD) indicating osteoporosis (T score ≤-2.5)
3. **ONE** of the following:
    a. Physician attestation of inadequate response to an adequate trial or adverse reaction to **ONE** oral bisphosphonate (see appendix for details)
    b. Contraindication to **ALL** oral bisphosphonates (see appendix for details)
    c. Member is at very high risk for fracture indicated by at least **ONE** of the following:
        i. History of fracture within the past 12 months
        ii. History of fractures while on osteoporosis therapy
        iii. History of multiple fractures
        iv. History of fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids)
        v. T-score less than −3.0

vi. High risk for falls
vii. History of injurious falls
viii. Very high fracture probability by FRAX® (fracture risk assessment tool) or other validated fracture risk algorithm

4. **ONE** of the following:
    a. Inadequate response to an adequate trial or adverse reaction with **ONE** or contraindication to **ALL** of the following:
        i. ibandronate injection
        ii. Prolia® (denosumab)
        iii. zoledronic acid 5 mg
    b. Diagnosis of severe osteoporosis defined as at least **ONE** of the following:
        i. History of fragility fracture within the past 12 months
        ii. History of fractures while on osteoporosis therapy
        iii. T-score less than -3.0
        iv. T-score of -2.5 or below plus a fragility fracture
5. Physician attestation of inadequate response, adverse reaction, or contraindication to Forteo® (teriparatide)

Continuation of Therapy

Recertification of Evenity® (romosozumab-aqqg) may only be issued for members who have not completed 12 months of treatment. The total treatment duration **should not exceed 12 months.**

Limitations

Approvals are limited to a maximum of 12 months of therapy

Appendices

Appendix A: 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.sheffield.ac.uk/FRAX/
- The estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture and 1.2 for hip fracture if glucocorticoid treatment is greater than 7.5 mg per day.

Appendix B: Clinical reasons to avoid oral bisphosphonate therapy

- Esophageal abnormality that delays emptying such as stricture of achalasia
- Active upper gastrointestinal problem (e.g., dysphagia, gastritis, duodenitis, erosive esophagitis, ulcers)
- Inability to stand or sit upright for at least 30 to 60 minutes
- Inability to take 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

References

1. Evenity [package insert]. Thousand Oaks, CA: Amgen; April 2020
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12. Barrionuevo P, Gionfriddo MR, Castaneda-Guarderas A, et al. Women's Values and Preferences Regarding Osteoporosis Treatments: A Systematic Review. J Clin Endocrinol Metab 2019; 104:1631
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Review History

11/20/2019 – Reviewed P&T
11/25/2019 – Reviewed and approved DCC
01/22/2020 – Approved P&T Mtg
09/22/2021 – Reviewed Sept P&T; references updated; no clinical updates
03/15/23 - Reviewed and updated for Mar P&T. Matched UPPL criteria. Effective 4/1/23.