

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

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy when obtained through the pharmacy benefit.		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>			

### 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:

#### Treatment/prevention of osteoporosis

Prescriber provides **medical records** documenting **ALL** of the following:

1. Appropriate diagnosis
2. Bone mineral density (BMD) indicating osteoporosis (T score  $\leq -2.5$ )
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  $\geq 20\%$  or hip fracture risk  $\geq 3\%$ .
- 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



2. Bisphosphonates. *Drug Facts and Comparisons*. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; March 21, 2019. Accessed April 10, 2019.
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4. Jeremiah MP, Unwin BK, Greenwald MH, et al. Diagnosis and management of osteoporosis. *Am Fam Physician*. 2015;92(4):261-268.
5. Watts NB, Bilezikian JP, Camacho PM, et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis. *Endocr Pract*. 2016;22 (Suppl 4):1-42.
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7. National Institute for Health and Care Excellence. Osteoporosis Overview. Last updated February 2018. Available at: <http://pathways.nice.org.uk/pathways/osteoporosis>. Accessed April 10, 2019.
8. FRAX<sup>®</sup> WHO fracture risk assessment tool. © World Health Organization Collaborating Centre for Metabolic Bone Diseases: University of Sheffield, UK. Available at: <https://www.sheffield.ac.uk/FRAX/>. Accessed April 10, 2019.
9. Fink HA, Gordon G, Buckley L, et al. 2017 American College of Rheumatology Guidelines for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis. *Arthritis Care Res*. 2017;69:1521-1537.
10. Ensrud KE, Crandall CJ. Osteoporosis. *Ann Intern Med* 2017;167(03): ITC17–ITC32.
11. Shoback D, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update. *J Clin Endocrinol Metab* 2020; 105
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
13. Viswanathan M, Reddy S, Berkman N, et al. Screening to Prevent Osteoporotic Fractures: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force. *JAMA* 2018; 319:2532

### 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.

