Mass General Brigham
Health Plan

Osteoporosis Agents
Evenity (romosozumab-aqqg)
Effective 01/04/2027

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Notes	**Evenity** is also available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria. Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview
Evenity (romosozumab-aqqg) is a sclerostin inhibitor 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
If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted when all of the following criteria are met:

Treatment of Osteoporosis:
ALL of the following:
1. Indication of treatment of postmenopausal osteoporosis
2. Bone mineral density (BMD) indicating osteoporosis (T score ≤-2.5)
3. **ONE** of the following:
    a. Inadequate response to an adequate trial or adverse reaction to **ONE** oral bisphosphonate
    b. Contraindication to **ALL** oral bisphosphonates
    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. Denosumab
        ii. Ibandronate injection
        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 last 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. Inadequate response, adverse reaction, or contraindication to teriparatide 560 mcg/2.24 mL (Bonsity, Forteo)

<u>Treatment of Osteoporosis in Biologic Male/Male Sex Assigned at Birth (off-label indication):</u>
ALL of the following:

1. Diagnosis of treatment of osteoporosis in biologic male/male sex assigned at birth
2. Bone mineral density (BMD) indicating osteoporosis (T score ≤-2.5)
3. **ONE** of the following:
    a. Inadequate response to an adequate trial or adverse reaction to **ONE** oral bisphosphonate
    b. Contraindication to **ALL** oral bisphosphonates
    c. Member is at very high risk for fracture indicated by at least **ONE** of the following:
        ix. History of fracture within the past 12 months
        x. History of fractures while on osteoporosis therapy
        xi. History of multiple fractures
        xii. History of fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids)
        xiii. T-score less than −3.0
        xiv. High risk for falls
        xv. History of injurious falls
        xvi. 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. 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. Inadequate response, adverse reaction, or contraindication to teriparatide 560 mcg/2.24 mL (Bonsity, Forteo)

Continuation of Therapy

Reauthorization 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

1. Authorizations are limited to a maximum of 12 months of therapy.

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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8. FRAX® 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.
12/11/24 – Reviewed and updated for P&T. Formatting update. Clarified appropriate diagnosis to specific diagnosis. Effective 1/6/25
07/09/25 – Reviewed and updated for P&T. Added new acceptable diagnosis. Clarified updated strength for Forteo. Removed appendices. Effective 8/11/25
4/15/26 – Reviewed and updated for P&T. Clarified trial of Prolia to denosumab. Clarified that either Bonsity or Forteo can be considered for teriparatide 560 mcg/2.24 mL. Effective 5/11/26

11/4/26 – Reviewed and updated for P&T. Removed indication of prevention of osteoporosis. Separated the two indications for Evenity as the treatment of osteoporosis in men is considered off-label. Updated formatting. Effective 1/4/27