

PHARMACY POLICY STATEMENT

Georgia Medicaid

DRUG NAME	Evenity (romosozumab-aqqg)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Evenity (romosozumab-aqqg) was initially approved by the FDA in 2019 for the treatment of osteoporosis in postmenopausal women at high risk for fracture, or in patients in whom other available osteoporosis therapy has failed or cannot be taken. Evenity is the only sclerostin inhibitor used for osteoporosis.

Evenity (romosozumab-aqqg) will be considered for coverage when the following criteria are met:

Osteoporosis

For **initial** authorization:

1. Member is a postmenopausal woman; AND
2. Member has a diagnosis of osteoporosis, as evidenced by one of the following:
 - a) Bone mineral density (BMD) T-score ≤ -2.5 or below in the lumbar spine, femoral neck, total proximal femur, or 1/3 radius;
 - b) Low-trauma spine or hip fracture (regardless of BMD);
 - c) Osteopenia (T-score between -1 and -2.5) with a fragility fracture of proximal humerus, pelvis, or distal forearm;
 - d) Osteopenia (T-score between -1 and -2.5) with FRAX fracture probability of $\geq 20\%$ for major osteoporotic fracture or $\geq 3\%$ for hip fracture; AND
3. Member meets one of the following:
 - a) Member has had an inadequate response to at least 12 months of an oral bisphosphonate (e.g., alendronate, risedronate) or an IV bisphosphonate (e.g., zoledronic acid (Reclast), ibandronate) OR
 - b) Member has very high risk for fracture (e.g., having multiple fractures, very low T score (-3.0 or below), T-score -2.5 or below plus fractures, fractures while taking osteoporosis drug, FRAX $> 30\%$ for major osteoporosis fracture or 4.5% for hip fracture^{2,4}); AND
4. Member does not have any of the following:
 - a) Uncorrected hypocalcemia
 - b) Prior heart attack (myocardial infarction) or stroke within the last year
 - c) Concurrent use with a parathyroid hormone analog (e.g., Forteo, Tymlos) or Prolia.
5. **Dosage allowed/Quantity limit:** 210 mg (as two 105 mg subQ injections) once a month. (2 syringes per 28 days)

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Evenity will not be reauthorized for continued therapy.

CareSource considers Evenity (romosozumab-aqqg) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
08/01/2019	New policy for Evenity created
07/31/2020	Osteoporosis definition was updated to accurately reflect current guidelines. Removed dental disease and history of hip fracture from excluded list. Added prior attack or stroke to excluded list per black box warning. Removed list of contraindications for oral bisphosphonates. Removed risk factor appendix. Specified length of oral bisphosphonate trial for 12 months. Specified 2 nd line trials to be any IV bisphosphonate or Prolia. Added no concurrent use with PTH or Prolia.
04/26/2022	Transferred to new template, clarified dose and quantity info, added new reference. Removed ibandronate for very high risk. Removed Prolia trial. Corrected very low T score from -3.5 to -3.0.
02/17/2023	Removed zoledronic acid trial for very high risk postmenopausal women.

References:

1. Evenity [prescribing information]. Thousand Oaks, CA: Amgen Inc.; April, 2020.
2. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis – 2020. *Endocr Pract.* 2020 May;26(5):564-570.
3. ClinicalTrials.gov. Identifier: NCT01575834. Efficacy and Safety of Romosozumab Treatment in Postmenopausal Women With Osteoporosis (FRAME). Available at: <https://clinicaltrials.gov/ct2/show/NCT01575834?term=NCT01575834&rank=1>.
4. Shoback D, Rosen CJ, Black DM, Cheung AM, Murad MH, Eastell R. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update. *J Clin Endocrinol Metab.* 2020;105(3):dga048.
5. Cosman, F., de Beur, S.J., LeBoff, M.S. et al. Clinician’s Guide to Prevention and Treatment of Osteoporosis. *Osteoporos Int* 25, 2359–2381 (2014).
6. Compston J, Cooper A, Cooper C, et al. UK clinical guideline for the prevention and treatment of osteoporosis. *Arch Osteoporos.* 2017;12(1):43. doi:10.1007/s11657-017-0324-5.
7. Gregson CL, Armstrong DJ, Bowden J, et al. UK clinical guideline for the prevention and treatment of osteoporosis. *Arch Osteoporos.* 2022;17(1):58. Published 2022 Apr 5. doi:10.1007/s11657-022-01061-5

Effective date: 07/01/2023
 Revised date: 02/17/2023