CareSource

PHARMACY POLICY STATEMENT **Georgia Medicaid**	
DRUG NAME	Evenity (romosozumab-aqqg)
BILLING CODE	J3111
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include alendronate, risedronate, ibandronate tablet and zoledronic acid QUANTITY LIMIT— 1 injection (210 mg) per 30 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Evenity (romosozumab-aqqg) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

OSTEOPOROSIS

For **initial** authorization:

1. Member is a postmenopausal woman with osteoporosis, as evidenced by **one** of the following[2]:
   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 ≥ 20% for major osteoporotic fracture or ≥ 3% for hip fracture; AND
2. Member meets **one** of the following conditions:
   a) Member has had an inadequate response to at least 12 months of an oral bisphosphonate (e.g., alendronate, risedronate);
   b) If oral bisphosphonate is not tolerated or contraindicated or if member has very high risk for fracture, must have a trial with IV bisphosphonate (e.g., zoledronic acid (Reclast), ibandronate) or Prolia (prior authorization required); AND
      Note: very high fracture risk is defined as having multiple fractures, T score -3.5 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].
3. 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.
4. **Dosage allowed:** 210 mg monthly.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
Evenity will not be reauthorized for continued therapy.

CareSource considers Evenity (romosozumab-aqqg) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Bone metastases from solid tumors
- Giant Cell Tumor of Bone
- Multiple Myeloma
- Paget's disease

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 2nd line trials to be any IV bisphosphonate or Prolia. Added no concurrent use with PTH or Prolia.

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):dgaa048.
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.

Effective date: 12/01/2020
Revised date: 07/31/2020