

PHARMACY POLICY STATEMENT

Indiana Medicaid

DRUG NAME	Evenity (romosozumab-aqqg)
BILLING CODE	J3590
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include alendronate, ibandronate and zoledronic acid QUANTITY LIMIT— 210 mg monthly for 12 months
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. Medication is intended to be used 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 (see *Appendix*), or who have failed or are intolerant to other available osteoporosis therapy; AND
2. Member's osteoporosis evidenced by one if the following:
 - a) Bone mineral density (BMD) T-score -2.5 or below at the total hip or femoral neck and either one moderate or severe vertebral fracture or two mild vertebral fractures;
 - b) BMD T-score less than or equal to -2.0 at the total hip or femoral neck and either two moderate or severe vertebral fractures or a history of a proximal femur fracture; AND
3. Member does **not** have ANY of the following:
 - a) Uncorrected hypocalcemia;
 - b) Dental disease
 - c) History of hip fracture; AND
4. Member was instructed to take at least 500 mg daily of calcium and at least 600 IU of vitamin D daily; AND
5. Member cannot take oral bisphosphonate therapies (i.e., alendronate and/or ibandronate) as evidenced by one or more of the following:
 - a) Esophageal dysmotility or varices;
 - b) Member is unable to stand or sit upright for 30-60 minutes;
 - c) Presence of anatomic or functional esophageal abnormalities that might delay tablet transit (e.g., achalasia, stricture, or dysmotility);
 - d) Presence of documented or potential GI malabsorption (e.g., gastric bypass procedures, celiac disease, Crohn's disease, infiltrative disorders, etc.);
 - e) Member has experienced intolerance to or treatment failure of one or more bisphosphonate medications;
 - f) Member has a history of non-adherence to oral bisphosphonate medications; AND
6. Member has had a documented trial and inadequate response to zoledronic acid.

7. **Dosage allowed:** 210 mg monthly.

If member meets all the requirements listed above, 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 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.

References:

1. Evenity [prescribing information]. Thousand Oaks, CA: Amgen Inc.; April, 2019.
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 – 2016. *Endocr Pract.* 2016;22(Suppl 4). Doi: 10.4158/EP161435.GL.
3. Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in men: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2012;97(6):1802-1822. Doi: 10.1210/jc.2011-3045.
4. Buckley L, Guyatt G, Fink HA, et al. 2017 American College of Rheumatology guideline for the prevention and treatment of glucocorticoid-induced osteoporosis. *Arthritis Rheumatol.* 2017;69(8):1521-1537. Doi: 10.1002/art.40137.
5. Bienz M, Saad F. Androgen-deprivation therapy and bone loss in prostate cancer patients: a clinical review. *Bonekey Rep.* 2015;4:Article 716. Doi: 10.1038/bonekey.2015.85.
6. 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>.
7. Michael R. McClung, et al. Sclerostin antibodies in osteoporosis: latest evidence and therapeutic potential. *Ther Adv Musculoskelet Dis.* 2017 Oct; 9(10): 263-270.
8. Kristie N. Tu, et al. Osteoporosis: A Review of Treatment Options. *P T.* 2018 Feb; 43(2): 92-104.

Effective date: 09/26/2019

Revised date: 08/01/2019

Appendix. Risk Factors for Fracture:

1. Prior fracture;
2. Age \geq 65;
3. Low body weight ($<$ 57.6 kg [127 lb]);
4. Family history of osteoporosis or fractures;
5. Smoking;
6. Early menopause;
7. Excessive alcohol intake (\geq 3 drinks daily);
8. Rheumatoid arthritis (confirmed diagnosis);
9. Secondary osteoporosis (e.g., type 1 diabetes, hypothyroidism, chronic liver disease);
10. Height loss (including unexplained) or kyphosis;
11. Patient's reliability, understanding, and willingness to accept interventions;
12. Glucocorticoid therapy equivalent to \geq 5 mg prednisone daily for 3 months or more;
13. Risk factors for falling.*

*Risk factors for falling can be any of the following:

- Neurologic disorders (e.g., Parkinson disease, seizure disorder, peripheral neuropathy, prior stroke, dementia, impaired gait and/or balance, autonomic dysfunction with orthostatic hypotension);
- Impaired vision;
- Impaired hearing;
- Frailty and deconditioning;
- Proximal myopathy;
- Sarcopenia;
- Medications (e.g., sedatives and hypnotics, antihypertensive agents, narcotic analgesics);
- Environmental factors (e.g., poor lighting, stairs, slippery floors, wet, icy, or uneven pavement, uneven roadways, electric or telephone cords, walking large dogs, being tripped up by small dogs, throw rugs, positioning in a wet or dry bathtub).