ALASKA MEDICAID
Prior Authorization Criteria

Evenity™ (romosozumab-aqqg)

FDA INDICATIONS AND USAGE[1]

Evenity™ (romosozumab-aqqg) is a sclerostin inhibitor that is indicated for the treatment of osteoporosis in postmenopausal women at high risk of fracture, defined by a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other osteoporosis therapies. Duration of treatment should be limited to no more than 12 monthly doses, due to a waning anabolic effect over time.

APPROVAL CRITERIA[1,2,3]

1. Patient is a postmenopausal woman at risk of fracture **AND**;
2. Patient has a diagnosis of osteoporosis defined by a bone mineral density T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 or a clinical diagnosis based on the history of a low trauma fracture and is at high risk for fracture **AND**;
3. Is being administered by a healthcare provider **AND**;
4. The patient has had a trial of an oral bisphosphonate (i.e. alendronate) for at least one year with less than optimal results, has a contraindication to their use, or the patient is unable to remain upright for at least 30 minutes, or intolerant to two bisphosphonate manufactures **AND**;
5. The patient has failed a prior treatment with or is intolerant to an injectable osteoporosis therapy (i.e. zolendronic acid) **AND;**
6. The prescriber has counseled patients that calcium and vitamin D should be adequately supplemented throughout treatment.

DENIAL CRITERIA[1]

1. Failure to meet approval criteria **OR**;
2. Patient has had myocardial infarction or stoke with in the preceding year **OR**;
3. Patient has hypocalcemia **OR**;
4. Treatment duration is for more than 12 monthly doses.

CAUTIONS[1]

- Monitor for major adverse cardiac events.
- Calcium and Vitamin D should be adequately supplemented throughout treatment.
- Monitor for osteonecrosis of the jaw.
- Hypersensitivity reactions such as, angioedema, erythema multiforme, rash, and dermatitis have been observed.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to an additional 9 months (authorization for approval cannot exceed 12 monthly doses)

QUANTITY LIMIT

- 2- 105mg syringes per month (210mg total)

REFERENCES / FOOTNOTES:

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 Medical Guidelines for clinical practice for the prevention and treatment of postmenopausal osteoporosis. Endocrine Practice. September 2016;22(4):1-42.
3. Cosman F, de Beur SJ, Leboff MS, et al. National Osteoporosis Foundation. Clinician's Guide to Prevention and Treatment of Osteoporosis. Washington, DC: National Osteoporosis Foundation; 2014 Osteoporosis Int. October 2014;25(10):2359-81.