

Evenity™ (romosozumab-aqqg)

When requesting Evenity™ (romosozumab-aqqg), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Evenity is indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

Coverage Guidelines

Treatment of osteoporosis in postmenopausal women

An individual must meet **BOTH** of the following criteria for approval:

- Must have one of the following criteria:
 - o Has a T-score at or below -2.5 at the lumbar spine, femoral neck, total hip and/or 33% radius (wrist) OR
 - o Had an osteoporotic fracture or a fragility fracture OR
 - o Has low bone mass (T-score between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip, and or 33% radius [wrist] and at high risk for fracture

AND

- Must have one of the following criteria:
 - o Has had an inadequate response to oral bisphosphonate therapy after a 12-month trial (e.g., ongoing and significant loss of bone mineral density [BMD], lack of BMD increase) OR
 - o Has had an osteoporosis fracture or a fragility fracture while receiving oral bisphosphonate therapy OR
 - o Has experienced intolerance to an oral bisphosphonate (e.g., severe gastrointestinal related adverse events, severe musculoskeletal-related adverse events, a femoral fracture) OR
 - o Is unable to take an oral bisphosphonate due to one of the following conditions: 1) cannot swallow or has difficulty swallowing, 2) cannot remain in an upright position post oral bisphosphonate administration; 3) has a pre-existing gastrointestinal medical condition (e.g., esophageal lesions, esophageal ulcers, abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]) OR
 - o Has tried ibandronate injection (Boniva IV) or zoledronic acid injection (Reclast) OR

- o Has severe renal impairment (creatinine clearance [CrCl] less than 35 mL/min) OR
- o Has chronic kidney disease

Approval duration: 12 months (lifetime)

Dosing Recommendation

The recommended dose of Evenity is 210 mg administered subcutaneously once every monthly in the abdomen, thigh or upper arm.

Two separate subcutaneous injections are needed to administer the total dose of 210 mg of Evenity.

References

1. Evenity™ injection for subcutaneous use [prescribing information]. Thousand Oaks, CA: Amgen; 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. *Endocrin Pract.* 2016;22(Suppl 4):1-42. Available at: <http://journals.aace.com/doi/pdf/10.4158/EP161435.GL>. Accessed on April 19, 2019.
3. Cosman F, de Beur SJ, LeBoff MS, et al. Clinician's guide to prevention and treatment of osteoporosis. *Osteoporos Int.* 2014;25:2359-2381. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4176573/pdf/198_2014_Article_2794.pdf. Accessed on April 19, 2019.
4. Qaseem A, Forciae MA, McLean RM, et al, Clinical Guidelines Committee of the American College of Physicians. Treatment of low bone density or osteoporosis to prevent fractures in men and women: a clinical practice guideline update from the American College of Physicians. *Ann Intern Med.* 2017;166(11):818-839.
5. Eastell R, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: an Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2019;104:1595-1622.