

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 factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

Coverage Guidelines

Treatment of osteoporosis in postmenopausal women

The individual must meet the following criteria for authorization:

- Has received no more than 12 monthly doses during this therapy course;
- Meets one of the following:
 - Had an osteoporotic fracture or a fragility fracture; OR
 - Has had a T-score at or below -2.5 at the lumbar spine, femoral neck, total hip and/or 33% radius (wrist); OR
 - 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 is at high risk for fractures)
- Meets one of the following:
 - Had an osteoporotic fracture or a fragility fracture; OR
 - Has tried an IV bisphosphonate agent (e.g., ibandronate injection [Boniva], zoledronic acid injection [Reclast]); OR
 - Has experienced inadequate efficacy with an oral bisphosphonate therapy after a 12-month trial (e.g., ongoing and significant loss of bone mineral density [BMD], lack of BMD increase); OR
 - Has experienced significant intolerance to an oral bisphosphonate therapy (e.g., severe gastrointestinal related adverse events, severe musculoskeletal-related adverse events, a femoral fracture); OR
 - 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
 - Has severe renal impairment (creatinine clearance [CrCl] <35 mL/min); OR
 - Has chronic kidney disease

Approval duration: 12 months (lifetime)

Dosing Recommendation

The recommended dose of Evenity is 210 mg administered subcutaneously once every month. The treatment duration for Evenity is 12 monthly doses.

References

1. Evenity™ injection for subcutaneous use [prescribing information]. Thousand Oaks, CA: Amgen; April 2020.
2. Shoback D, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: an Endocrine Society guideline update. *J Clin Endocrinol Metab.* 2020;105(3):587-594.

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