Evenity (romosozumab-aqqg)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Evenity (romosozumab-aqqg)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Evenity (romosozumab-aqqg) may be approved for the following:

I. Individual is a postmenopausal female with the following:
   A. A diagnosis of osteoporosis (defined as a bone mineral density (BMD) T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to a young-adult reference population OR a clinical diagnosis based on history of a low trauma fracture (fragility fracture) at high risk for fracture;

AND

II. The individual meets one of the following:
   A. Individual is at very high risk for fracture as defined by one or more of the following (AACE/ACE 2020):
      1. Recent fracture (within the past 12 months)
      2. Fractures while on approved osteoporosis therapy
      3. Multiple fractures
      4. Fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoids)
      5. Very low T-score (less than -3.0)
      6. High risk for falls or history of injurious falls
      7. Very high fracture probability by FRAX (fracture risk assessment tool) (e.g. major osteoporosis fracture >30%, hip fracture >4.5%) or other validated fracture risk algorithm;

   OR

   B. Individual has been refractory to a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of an oral bisphosphonate; **OR**
   C. Individual is intolerant to or has a contraindication to an oral bisphosphonate as defined by:
      1. Hypersensitivity to TWO oral bisphosphonates (one of which must be alendronate); **OR**
      2. Inability to stand or sit upright for at least 30 minutes; **OR**
      3. Pre-existing gastrointestinal disorders (Barrett's esophagus, hypersecretory disorders, delayed esophageal emptying, atrophic gastritis, etc.); **OR**

4. Severe renal insufficiency as defined by creatinine clearance less than 35 mL/min for alendronate agents and zoledronic acid or creatinine clearance less than 30 mL/min for risedronate and ibandronate;

AND

III. Individual has been refractory to, is intolerant of, or has a contraindication to one of the following:
   A. Prolia (denosumab); **OR**
   B. Forteo or Bonsity (teriparatide); **OR**
   C. Tymlos (abaloparatide);

AND

IV. Individual is not using Evenity (romosozumab-aqqg) in combination with any of the following:
   A. Prolia (denosumab);
   B. Bisphosphonates;
   C. Evista (raloxifene);
   D. Miacalcin/Fortical (calcitonin nasal spray);
   E. Reclast (zoledronic acid);
   F. Forteo or Bonsity (teriparatide);
   G. Tymlos (abaloparatide);

AND

V. Individual has utilized Evenity (romosozumab-aqqg) for a total duration of less than 12 months in their lifetime.

Requests for Evenity (romosozumab-aqqg) may not be approved when the above criteria are not met and for all other indications.

Notes:

1. Higher risk for fracture may be defined as:
   A. History of osteoporotic fracture; or
   B. Multiple risk factors for fractures, including but not limited to: Prior low-trauma fracture as an adult, advanced age, gender, ethnicity, low bone mineral density, low body weight, family history of osteoporosis, use of glucocorticoids (daily dosage equivalent to 5 mg or greater prednisone for at least 3 months), cigarette smoking, excessive alcohol consumption (3 or more drinks per day), secondary osteoporosis (such as, rheumatoid arthritis), early menopause, height loss or kyphosis, fall risk and low calcium intake; or
   C. Failure or intolerance to other osteoporosis therapies.
2. A failure of other osteoporosis therapies, otherwise known as refractory disease, may be defined as a decline in BMD while on therapy (≥5%) or a fragility fracture while on therapy.
3. There is a lack of long term safety and efficacy data with Evenity, therefore, the label limits treatment duration to one year (12 monthly doses).

4. Evenity (romosozumab-aqqg) has a black box warning for potential risk of myocardial infarction (MI), stroke, and cardiovascular death. It should not be initiated in patients who have had an MI or stroke within the preceding year and should be discontinued if a patient experiences an MI or stroke during therapy.

Key References:

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4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Eastell R, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Clinical Practice Guideline, The Journal of Clinical Endocrinology & Metabolism, Volume 104, Issue 5, May 2019, Pages 1595–1622, https://doi.org/10.1210/jc.2019-00221
6. Shoback D, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update, The Journal of Clinical Endocrinology & Metabolism, Volume 105, Issue 3, March 2020, Pages 587-594.
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
8. Cosman F, Crittenden DB, Adachi JD, et al. Romosozumab treatment in postmenopausal women with osteoporosis. *N Engl J Med* 2016; 375(16):1532-1543.
9. Lewiecki EM, Dinavahi RV, Lazaretti-Castro M, et al. One Year of Romosozumab Followed by Two Years of Denosumab Maintains Fracture Risk Reductions: Results of the FRAME Extension Study. J Bone Miner Res. 2018 Dec 3. doi: 10.1002/jbmr.3622. [Epub ahead of print].
10. Saag KG, Petersen J, Brandi ML, et al. Romosozumab or Alendronate for Fracture Prevention in Women with Osteoporosis. N Engl J Med 2017; 377(15):1417-27.
11. FDA Advisory Committee: Bone, Reproductive and Urologic Drugs Advisory Committee. FDA Briefing Document romosozumab. January 16, 2019.