Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

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. Has been refractory to a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of an oral bisphosphonate; **OR**
   B. 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. Uncorrected hypocalcemia; **OR**
      5. Severe renal insufficiency as defined by creatinine clearance less than 35 mL/min for alendronate agents 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**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

B. Forteo (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 (teriparatide);
G. Tymlos (abaloparatide);

AND

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

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. In the absence of fragility fracture, BMD T-Scores > -2.5 (closer to 0 or positive) are not considered osteoporotic.
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.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

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4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
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7. 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].
8. 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.
9. FDA Advisory Committee: Bone, Reproductive and Urologic Drugs Advisory Committee. FDA Briefing Document romosozumab. January 16, 2019. Available at: https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/ucm629455.htm Accessed April 10, 2019.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.
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