Original Effective Date: 06/01/2019
Current Effective Date: 03/27/2026
Last P&T Approval/Version: 01/28/2026
Next Review Due By: 07/2026
Policy Number: C17324-A

Evenity (romosozumab-aqqg)

PRODUCTS AFFECTED

Evenity (romosozumab-aqqg)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Osteoporosis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. OSTEOPOROSIS:
   1. Documented diagnosis of postmenopausal osteoporosis in women who are at a high risk of fracture

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MOLINA REVIEWER NOTE: High risk of 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.
AND

2. a) The member has had a T-score (current or at any time in the past) at or below -2.5 at the lumbar spine, femoral neck, total hip, and/or 33% (one-third) radius (wrist)
   OR
   b) The member has had an osteoporotic fracture or a fragility fracture of the spine, hip, proximal humerus, pelvis, or distal forearm
   OR
   c) The member has low bone mass (T-score [current or at any time in the past] between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip and/or 33% [one-third] radius [wrist]) and the prescriber determines the member is at high risk for fracture
   AND
3. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Evenity (romosozumab-aqqg) include: Hypersensitivity (e.g., angioedema, erythema multiforme, urticaria) to romosozumab or any component of the formulation, and uncorrected hypocalcemia, Evenity should not be initiated in patients who have had a myocardial infarction or stroke within the preceding year]
   AND
4. Documentation of trial and failure (12-month total trial), contraindication, or serious side effects to bisphosphonate therapy (oral and/or IV). Submit documentation including medication(s) tried and dates of trial(s).
   NOTE: Treatment failure is defined by progression of bone loss as documented by bone density measurements (BMD) after at least 12 months of therapy OR occurrence of an osteoporotic fracture after having been compliant on at least 12 months of therapy on an oral bisphosphonate.
   AND
5. Treatment duration has not exceeded a total of 12 months
   AND
6. Documentation of trial/failure or serious side effects to a majority (not more than 3) of the preferred alternatives for the given diagnosis (i.e., denosumab and biosimilars, teriparatide, Tymlos (abaloparatide)). Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

CONTINUATION OF THERAPY:
NA

DURATION OF APPROVAL:
Initial authorization: 12 months, Continuation of therapy: NA

PRESCRIBER REQUIREMENTS:
None

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
210 mg subcutaneously once every month for 12 doses

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable products administered in a place of service that is a non-hospital facility-based location.

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DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

DRUG CLASS:
Sclerostin Inhibitors

FDA-APPROVED USES:
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
Limitations of Use: Limit duration of use to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Evenity, a sclerostin inhibitor, 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.[1]
According to the Evenity prescribing information, the anabolic effect of Evenity wanes after 12 monthly doses of therapy. Therefore, limit the duration of use to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive therapy (e.g., alendronate) should be considered.
Many guidelines are available regarding the management of postmenopausal osteoporosis.[2-5] In general, the guidelines recommend bisphosphonate therapy initially for women in whom pharmacologic therapy is warranted (e.g., women at high risk of fractures) to reduce the risk of fractures. For patients who are extremely high risk of fracture (e.g., previously experienced an osteoporotic or fragility fracture) other osteoporosis therapies are recommended. Other agents are also recommended for women who cannot take bisphosphonate therapy (e.g., patients with severe renal impairment [creatinine clearance < 35 mL/min], chronic kidney disease) or who have an underlying gastrointestinal condition (e.g., esophageal lesions). In general, osteoporosis is defined by the presence of fragility fractures or among women with a T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, and/or 33% (one-third) radius.[2] Therapy is also recommended among women who have a T-score between -1.0 and -2.5 if a substantial risk for major osteoporotic fracture is present (e.g., Fracture Risk Assessment Tool [FRAX®] score suggests high risk). An estimated 54 million Americans have osteoporosis or some other form of low bone mass.
Osteoporosis is diagnosed most commonly via a dual energy x-ray absorptiometry (DEXA or DXA) scan which characterizes bone density and compares with normal values for healthy young adults of the same sex. From this comparison, a “t-score” is derived based on the number of standard deviations

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(SD) an individual falls above or below the young adult mean.

Numerous brand and generic pharmacotherapies are marketed to treat osteoporosis via varied mechanisms. Initiation of pharmacotherapy is generally recommended with a history of a fracture, a t-score < -2.5, or a t-score between -1 and -2.5 and a high probability of any major osteoporosis- related fracture. Lacking robust head-to-head efficacy data, a stepwise approach is often chosen in disease management. Choice of therapy should be based upon efficacy, safety, cost, convenience, and other patient- related factors.

Common therapies:

Oral bisphosphonates (e.g., Actonel, Atelvia, Boniva, Fosamax): First-line treatment of choice due to efficacy, favorable cost, generic availability, and long-term safety data

Intravenous bisphosphonates (e.g., Boniva, Reclast): May be considered as alternate first line therapy for patients with contraindications to oral bisphosphonates (except chronic kidney disease); Less frequent dosing may also increase adherence

RANK-L Inhibitors (e.g., Prolia): Prolia may be considered as an alternative to intravenous bisphosphonates for patients at high fracture risk, have difficulty with the dosing of oral bisphosphonates, prefer to avoid IV bisphosphonates due to side effects, or have impaired renal function

Selective Estrogen Receptor Modulators or SERMs (e.g., Evista, Duavee): Generally reserved for prevention of bone loss; Alternative to bisphosphonates for treatment in women who: Cannot tolerate or are not candidates for any bisphosphonates, Are also at high risk for invasive breast cancer

Estrogens and Progestins (e.g., Premarin, Climara Pro): Estrogens are approved for prevention, not treatment of osteoporosis. Progestins have a small benefit compared to estrogen and no increased efficacy when combined with estrogen compared to estrogen alone

Calcitonins (e.g., Miacalcin, Fortical): Considered less effective than bisphosphonates and are not typically used for treatment

Parathyroid Hormone and Analogs (e.g., Forteo and Tymlos): Anabolic agents. Rarely used as first line therapy due to cost, subcutaneous route of administration, long-term safety concerns, and availability of other agents. May be considered as first line for patients with severe osteoporosis. Treatment is limited to 24 months, thus patients who are treated with these agents are typically also treated with bisphosphonates after discontinuing Forteo to preserve bone density gains.

Evenity is an anabolic monoclonal antibody that inhibits the activity of sclerostin, a regulatory factor in bone metabolism, resulting in increased bone formation and decreased bone resorption (to a lesser extent). Evenity should be considered for patients unable to use oral therapy and as initial therapy for patients at very high fracture risk.

Efficacy

Evenity's approval was based on results from two clinical trials involving more than 11,000 women with postmenopausal osteoporosis. Study 1 (NCT01575834) Randomized, double-blind, placebo-controlled study in women aged 55-90 years with bone mineral density (BMD) T-scores of -2.5 or less at the total hip or femoral neck. A total of 3,589 women received Evenity and 3,591 received placebo. Following 12 months, women in both arms were transitioned to open-label anti-resorptive therapy with Prolia (denosumab) for 12 months. Women received 500-1,000 mg of calcium and 600- 800 international units of vitamin D daily. The primary endpoints were new vertebral fracture at 12 and 24 months.

The trial demonstrated a reduction in the incidence of clinical fractures, which was a composite endpoint of symptomatic vertebral and nonvertebral fractures, but 88% of these fractures were nonvertebral and the incidence of nonvertebral fractures was not statistically significant at 12 or 24 months. Evenity patients did experience an increase BMD at the lumbar spine, total hip, and femoral neck compared with placebo-treated patients, with increases maintained following transition to 12 months of Prolia. No difference in response was noted based on age, baseline BMD, or geographic region. In the absence of Prolia, BMD returned to baseline levels within 12 months of Evenity discontinuation. Evenity also increased BMD by 12.7% at the lumbar spine, 5.8% at the total hip, and 5.2% at the femoral neck. Study 2 (NCT01631214) Randomized, double-blind, alendronate-controlled study in women aged 55-90 years with bone mineral density (BMD) T-scores of -2.5 or less at the total hip or femoral neck and either o One moderate or severe vertebral fracture, or o Two mild vertebral fractures, or o BMD T-score less than or equal to -2.0 at the total hip or femoral neck

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and either Two moderate or severe vertebral fractures, or A history of a proximal femur fracture. A total of 2,046 women received Evenity and 2,047 received oral alendronate 70 mg weekly. All women received 500-1,000 mg of calcium and 600-800 international units of vitamin D daily.
Following 12 months, women in both arms were transitioned to open-label alendronate 70 mg weekly. The coprimary endpoints were incidence of morphometric vertebral fracture at 24 months and time to the first clinical fracture through the first analysis period (ended when at least 330 subjected had a clinical fracture and all subjected had completed the 24-month visit.
Evenity significantly reduced the risk of clinical fracture through the end of the primary analysis. In the Evenity followed by alendronate group, the risk of nonvertebral fracture was also reduced, with a hazard ratio of 0.81 (95% CI: 0.66, 0.99; p = 0.04). Evenity also increased BMD by 8.7% at the lumbar spine, 3.3% at the total hip, and 3.2% at the femoral neck.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Evenity (romosozumab-aqqg) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Evenity include: hypocalcemia, known hypersensitivity (angioedema, erythema multiforme, dermatitis, rash, and urticaria) to Evenity.

Exclusions/Discontinuation:
Do not use concurrently with bisphosphonates, RANKL inhibitor (e.g., denosumab), or parathyroid hormone analog (e.g., Forteo, Tymlos).
If a patient experiences an MI or stroke during therapy, romosozumab should be discontinued.

OTHER SPECIAL CONSIDERATIONS:
Evenity (romosozumab-aqqg) has a Black Boxed Warning: Romosozumab may increase the risk of MI, stroke, and cardiovascular death. Romosozumab should not be initiated in patients who have had an MI or stroke within the preceding year. Consider whether the benefits outweigh the risks in patients with other cardiovascular risk factors. If a patient experiences an MI or stroke during therapy, romosozumab should be discontinued.

Evenity (romosozumab-aqqg) should be administered by a healthcare provider.

Patients should be counseled to concurrently take calcium (1000 mg) and vitamin D (400-1200 international units) supplements in conjunction with romosozumab.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
J3111	Injection, romosozumab-aqqg, 1 mg

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AVAILABLE DOSAGE FORMS:
Evenity SOSY 105MG/1.17ML prefilled syringe

REFERENCES

1. Evenity (romosozumab-aqqg) injection, for subcutaneous use [prescribing information]. Thousand Oaks, CA: Amgen; October 2024.
2. Camacho, P., Petak, S., Binkley, N., Diab, D., Eldeiry, L., Farooki, A., Harris, S., Hurley, D., Kelly, J., Lewiecki, E., Pessah-Pollack, R., McClung, M., Wimalawansa, S. and Watts, N., 2020. American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis—2020 Update. Endocrine Practice, 26, pp.1-46.
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 22, 2020.
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 EndocrinolMetab. 2019;104:1595-1622.
6. Qaseem, A., Hicks, L. A., Etxeandia-Ikobaltzeta, I., Shamliyan, T., & Cooney, T. G. (2023). Pharmacologic treatment of primary osteoporosis or low bone mass to prevent fractures in adults: A living clinical guideline from the American College of Physicians. Annals of Internal Medicine, 176(2), 224–238. doi:10.7326/m22-1034

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information	Q1 2026
REVISION- Notable revisions: Required Medical Information Contraindications/Exclusions/Discontinuation References	Q3 2025
REVISION- Notable revisions: Required Medical Information Other Special Considerations References	Q3 2024
REVISION- Notable revisions: Required Medical Information Quantity Other Special Considerations Available Dosage Forms References	Q3 2023

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REVISION- Notable revisions: Required Medical Information Background Contraindications/Exclusions/Discontinuation References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file

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