

This guideline may contain custom content that has been modified from the MCG care guidelines and has not been reviewed or approved by MCG Health.

** Please note: Alignment's policy is to make decisions on coverage based on the Centers for Medicare and Medicaid Services (CMS) regulations and guidance, benefit plan documents and contracts, and the member's medical history and condition. If CMS does not have a position addressing a service, Alignment makes coverage decisions based on Alignment's or the delegator's policy. Benefits may vary based on contract, and individual member benefits must be verified. Alignment determines medical necessity if the benefit exists and no contract exclusions are applicable. Although Alignment's policy is consistent with CMS's regulations and guidance, their payment methodology may differ from Medicare. Alignment reserves the right to reimburse the most cost effective durable medical equipment item that is appropriate to the member's medical needs and condition. The decision is based on the member's current medical condition.*

AHC Romosozumab

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Clinical Indications

- Romosozumab may be indicated when **ALL** of the following are present :
 - Postmenopausal female and **ALL** of the following [A] :
 - Documented osteoporosis, as indicated by **1 or more** of the following:
 - Femoral neck, spine, or total hip bone mineral density T-score between -1.0 to -2.5 and **1 or more** of the following:
 - Fracture Risk Assessment Tool (FRAX®) [B] 10-year probability for major osteoporotic fracture of 20% or greater
 - Fracture Risk Assessment Tool (FRAX®) [B] 10-year probability of hip fracture greater than country-specific threshold (eg, 3% or greater in the United States) [C]
 - Femoral neck, spine, or total hip bone mineral density T-score -2.5 or less
 - Hip or vertebral fragility (ie, low-trauma) fracture in patient 50 years or older
 - Patient at high risk for fracture, as indicated by **1 or more** of the following [D] :
 - Failure of [E] , inability to tolerate, or contraindication to other available osteoporosis therapy, including **1 or more** of the following :
 - Abaloparatide
 - Calcitonin
 - Denosumab
 - Intravenous bisphosphonate (eg, ibandronate, zoledronic acid)
 - Oral bisphosphonate (eg, alendronate, risedronate, ibandronate)
 - Raloxifene
 - Teriparatide
 - Risk factors for fracture, as indicated by **1 or more** of the following:
 - Member has a BMD T-score of -2.5 or lower AND a history of osteoporotic fracture
 - Member has a history of multiple osteoporotic vertebral fractures
 - Member had osteoporotic fractures while receiving a FDA approved treatment for osteoporosis
 - Member has a history of osteoporotic fracture in the past 12 months
 - Member has a BMD T-score of -3.0 or lower [F]

- FRAX 10-year probability of major osteoporotic fracture $\geq 30\%$ [G]
- FRAX 10-year probability of hip fracture $\geq 4.5\%$ [H]
- No hypocalcemia
- No myocardial infarction or stroke within previous 12 months
- Patient not pregnant or breast-feeding
- Dose does not exceed 210 mg monthly for total duration of one year.

Application

- This policy applies to the following states: Arizona, California, Nevada, North Carolina, and Texas.
- Please refer to the CMS website for the most current applicable National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

Committee Approval

- 01/09/2024, 02/20/2025

Policy Revision History

- 02/21/2023: Creation date
- 10/03/2023, 12/08/2023: Revision
- 11/12/2024: Annual review, Applicable states updated, Florida removed

References

1. Evenity (romosozumab-aqqg) injection. Physician Prescribing Information [Internet] Amgen Inc. 2020 Apr Accessed at: <https://www.evenity.com/>. [created 2019; accessed 2021 Nov 17] [Context Link 1]
2. Camacho PM, et al. American Association of Clinical Endocrinologists/American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis - 2020 update. *Endocrine Practice* 2020;26(5):564-570. DOI: 10.4158/GL-2020-0524. (Reaffirmed 2021 Oct) [Context Link 1, 2, 3, 4]
3. Shoback D, Rosen CJ, Black DM, Cheung AM, Murad MH, Eastell R. Pharmacological management of osteoporosis in postmenopausal women: an Endocrine Society Guideline update. *Journal of Clinical Endocrinology and Metabolism* 2020;105(3):dgaa048. DOI: 10.1210/clinem/dgaa048. (Reaffirmed 2021 Oct) [Context Link 1, 2]
4. Compston JE, McClung MR, Leslie WD. Osteoporosis. *Lancet* 2019;393(10169):364-376. DOI: 10.1016/S0140-6736(18)32112-3. [Context Link 1]
5. Licata AA. Bone density, bone quality, and FRAX: changing concepts in osteoporosis management. *American Journal of Obstetrics and Gynecology* 2013;208(2):92-96. DOI: 10.1016/j.ajog.2012.10.874. [Context Link 1, 2, 3]
6. Eastell R, Rosen CJ, Black DM, Cheung AM, Murad MH, Shoback D. Pharmacological management of osteoporosis in postmenopausal women: an Endocrine Society* clinical practice guideline. *Journal of Clinical Endocrinology and Metabolism* 2019;104(5):1595-1622. DOI: 10.1210/je.2019-00221. (Reaffirmed 2021 Jun) [Context Link 1, 2, 3]

Footnotes

[A] For women with postmenopausal osteoporosis, romosozumab is administered subcutaneously once monthly for a total of 12 doses. The duration of treatment should be limited to 12 months.(1) Specialty society guidelines recommend an antiresorptive agent, such as a bisphosphonate, after discontinuation of romosozumab because of potential for bone loss after discontinuation.(2)(3) A specialty society guideline and a review article do not recommend concomitant use of osteoporotic medications.(2)(4) [A in Context Link 1]

[B] The Fracture Risk Assessment Tool (FRAX®) was developed using demographic and clinical risk factors to predict a patient's nationality-adjusted 10-year risk for developing a hip fracture or major osteoporotic fracture.(5) [B in Context Link 1, 2]

[C] The Fracture Risk Assessment Tool (FRAX®) country-specific threshold should be used in countries other than the United States.(5) [C in Context Link 1]

[D] Bisphosphonates are first-line therapy for most women with postmenopausal osteoporosis with indications for treatment.(6) Two specialty society guidelines suggest that patients at very high risk of fracture be treated with alternate osteoporosis treatments.(2)(6) One guideline recommends treatment with abaloparatide, denosumab, romosozumab, teriparatide, or zoledronate for patients with postmenopausal osteoporosis and very high fracture risk, as defined by recent fractures, fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (eg, long-term glucocorticoids), very low bone mineral density T-score (eg, less than -3.0), a high risk for falls or history of injurious falls, or a very high fracture probability by Fracture Risk Assessment Tool (FRAX®) or other validated fracture risk algorithm (eg, major osteoporosis fracture risk greater than 30% or hip fracture risk greater than 4.5%). The authors note limited evidence for defining patients at very high risk.(2) A second guideline

recommends initial treatment with bisphosphonates for most postmenopausal women at high risk of fractures, with denosumab as an alternative. The authors recommend teriparatide, abaloparatide, or romosozumab for those at very high risk of fractures (eg, history of multiple vertebral fractures).(3)(6) [D in Context Link 1]

[E] Inadequate response is defined as a new fracture in a compliant member or significant loss of bone mineral density on follow-up scans. [E in Context Link 1]

[F] Measured at the femoral neck, total hip, lumbar spine, or 33% radius [F in Context Link 1]

[G] FRAX® Fracture Risk Assessment Tool. <https://www.sheffield.ac.uk/FRAX/index.aspx> [G in Context Link 1]

[H] FRAX® Fracture Risk Assessment Tool. <https://www.sheffield.ac.uk/FRAX/index.aspx> [H in Context Link 1]

Codes

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