

Romosozumab

ACG: A-1008 (AC)

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MCG Health
Ambulatory Care
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Clinical Indications

- Romosozumab may be indicated when **ALL** of the following are present(1)(2)(3)(4)(5)(6):
 - Postmenopausal female and **ALL** of the following[A](16)(17)(20)(21)(22)(23)(24):[\[A\]](#)
 - Documented osteoporosis, as indicated by **1 or more** of the following(6)(8)(16)(19)(32)(33)(34)(35):
 - 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]
 - Fragility fracture of proximal humerus, pelvis, or distal forearm
 - Femoral neck, spine, or total hip bone mineral density T-score -2.5 or less
 - Hip or vertebral fragility (ie, low-trauma) fracture
 - Need for therapy with romosozumab, as indicated by **1 or more** of the following[D]:
 - Failure of, 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(8)(16)(19)(30)(38)(39)(40):
 - Alcohol intake of 3 or more drinks per day
 - BMI less than 20  BMI Calculator
 - Current cigarette use
 - Frequent falls (2 or more falls in the previous 1 year)
 - Glucocorticoid use of 3 months' or greater duration
 - Parental hip fracture
 - Personal history of fragility or osteoporotic fracture
 - Rheumatoid arthritis (confirmed diagnosis)
- No hypocalcemia
- No myocardial infarction or stroke within previous 12 months
- Patient not pregnant or breast-feeding

Evidence Summary

Background

Romosozumab is a humanized monoclonal antibody that inhibits sclerostin, stimulating bone formation and decreasing bone resorption.(1)(7)(8)(9) **(EG 2)**

Romosozumab may increase the risk of myocardial infarction, stroke, and cardiovascular death. It should not be initiated within 1 year of a myocardial infarction or stroke.(1)(9)(10)(11)(12) **(EG 1)**

Romosozumab is associated with osteonecrosis of the jaw. Risk factors include poor oral hygiene, cancer, and radiation therapy.(1) **(EG 2)**

Criteria

The evidence for the clinical indications found in this guideline includes 31 published peer reviewed articles and 8 specialty society or other evidence-based guidelines.

For women with postmenopausal osteoporosis, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** A systematic review and network meta-analysis that included 6 randomized controlled trials evaluating romosozumab, 5 of which were conducted in women with postmenopausal osteoporosis, found that romosozumab was associated with reduced vertebral fracture risk as compared with placebo. The combination of romosozumab for 1 year followed by alendronate was associated with reduced vertebral and hip fracture risk as compared with placebo and with reduced vertebral fracture risk as compared with bisphosphonates alone.(25) **(EG 1)** A randomized trial of 7180 postmenopausal women with osteoporosis (T-score of -2.5 to -3.5) compared treatment with romosozumab or placebo and found, at 12-month follow-up, that treatment with romosozumab was associated with fewer new vertebral fractures and increased bone mineral density at the lumbar spine, total hip, and femoral neck compared with placebo. At 12 months, all patients were switched to maintenance treatment

with denosumab; at 24-month follow-up, the patients initially treated with romosozumab had a significantly decreased risk of new vertebral fractures compared with those initially treated with placebo.(20) **(EG 1)** In an extension of this study, all patients were continued on denosumab for an additional 12 months; at 36-month follow-up, patients initially treated with romosozumab had a significantly decreased risk of new fracture (vertebral and nonvertebral) and increased bone mineral density at the lumbar spine, hip, and femoral neck compared with patients initially treated with placebo.(26) **(EG 1)** A subset analysis of the original randomized controlled trial evaluating the 6.9% of enrolled patients who were Japanese confirmed similar decreased vertebral and nonvertebral fracture risk at 36 months.(27) **(EG 1)** A randomized trial of 4093 postmenopausal women with osteoporosis and a history of at least one fragility fracture compared treatment with 12 months of romosozumab with oral alendronate (followed by an additional 12 months of oral alendronate in all patients) and found, at 24-month follow-up, that romosozumab was associated with a lower risk of new vertebral fractures, clinical fractures (defined as nonvertebral and symptomatic vertebral), nonvertebral fractures, and hip fractures compared with alendronate; romosozumab was also associated with improved bone mineral density from baseline compared with alendronate.(21) **(EG 1)** A phase III randomized trial of 436 postmenopausal women with osteoporosis (T-score of -2.5 or less) and a previous fracture (all of whom had received oral bisphosphonate therapy for at least 3 years, including alendronate in the year prior to the study) compared further therapy with romosozumab or teriparatide and found, at 12-month follow-up, that romosozumab was associated with improved gains in hip bone mineral density compared with teriparatide.(22) **(EG 1)** A specialty society guideline recommends initiating pharmacologic therapy for postmenopausal patients with low bone mass and a history of hip or spine fragility fracture or high risk for fracture. The guideline suggests that patients at very high fracture risk (eg, fracture within the past 12 months, high risk for falls, fractures while on osteoporosis pharmacotherapy) be treated with abaloparatide, denosumab, romosozumab, teriparatide, or zoledronate, but notes that there is limited evidence for defining who is at very high risk.(16) **(EG 2)** Other specialty society guidelines and review articles recommend initial treatment with bisphosphonates for most postmenopausal women with osteoporosis at high fracture risk but suggest romosozumab for those at very high fracture risk, such as women with severe osteoporosis or multiple vertebral fractures.(4)(17)(28)(29)(30) **(EG 2)** An expert review of sequential treatment options for patients with osteoporosis at very high risk of fracture recommends treatment with either an anabolic agent (teriparatide or abaloparatide) or a dual-action agent (romosozumab) for 1 to 2 years followed by antiresorptive treatment thereafter.(31) **(EG 2)**

Inconclusive or Non-Supportive Evidence

For healing of bone fractures, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A phase II randomized controlled trial comparing 3 doses of romosozumab (70 mg, 140 mg, or 210 mg) with placebo in 332 patients age 55 to 94 years with unilateral intertrochanteric or femoral neck fracture undergoing internal fixation found no significant differences between groups in functional mobility improvement, as measured by the Timed Up and Go test, over 6 to 20 weeks of follow-up. In addition, there were no differences between the romosozumab and placebo groups in rates of fracture healing at 24 weeks and 52 weeks of follow-up. The authors recommended additional studies evaluating fracture repair augmentation in patients at risk of fracture nonunion or delayed union.(13) **(EG 1)** A phase II randomized controlled trial comparing 9 doses of romosozumab with placebo in 402 adult patients with fresh unilateral tibial fractures undergoing fixation found no differences between groups in rates of radiographic healing at 24 or 52 weeks of follow-up or time to radiographic healing. The authors recommended additional studies of romosozumab in patients at risk of fracture complications.(14) **(EG 1)**

For osteoporosis in males, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A phase III randomized trial of 245 men with osteoporosis compared treatment with romosozumab or placebo and found, at 12-month follow-up, that romosozumab was associated with increased bone mineral density in the lumbar spine, total hip, and femoral neck compared with placebo. However, the authors noted that studies demonstrating a reduction in fractures have not been performed in men.(15) **(EG 1)**

Rationale

Use of this MCG care guideline helps the clinician determine if a particular treatment, medication, or service might be appropriate for a specific patient, taking into account their unique health complexities.

Use of these evidence-based clinical criteria to support decision making benefits the patient by identifying patient-specific complex clinical factors and conditions, promoting personalized treatment. Utilizing evidence-based clinical criteria promotes patient safety by helping ensure that potential patient benefits outweigh the

risks. In addition, the use of evidence-based guidelines can increase consistency in treatment thresholds, leading to less variation in care and promoting equitable treatment among patients.

Related CMS Coverage Guidance

This guideline supplements but does not replace, modify, or supersede existing Medicare regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Code of Federal Regulations (CFR): 42 CFR 419.22(41); 42 CFR 422.101(42)

Internet-Only Manual (IOM) Citations: CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 14 - Medical Devices(43); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services(44); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage(45)

Medicare Coverage Determinations: Medicare Coverage Database(46)

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Footnotes

[A] The duration of treatment with romosozumab 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.(16)(17)(18) A specialty society guideline and a review article do not recommend concomitant use of osteoporotic medications.(16)(19) [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.(36) [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.(36) [C in Context Link 1]

[D] Bisphosphonates are first-line therapy for most women with postmenopausal osteoporosis with indications for treatment.(37) Two specialty society guidelines suggest that patients at very high risk of fracture be treated with alternate osteoporosis treatments.(16)(37) 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.(16) 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).(17)(37) [D in Context Link 1]

Codes

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