EVENITY®
(romosozumab-aqqg)
injection 105 mg/1.17 mL

Prior Authorization Tip Sheet

This tip sheet provides some suggestions that may help you when completing a PA request for EVENITY®. However, because payer requirements differ, this list is not all inclusive. Consult the health plan's policy for specific PA criteria and documentation requirements.

Determine Fulfillment Pathway

Most payers have **different** PA forms for the pharmacy benefit and the medical benefit. It is important to determine the appropriate fulfillment pathway before starting the PA process.

Medical Benefit (Part B/commercial) fulfilled through:

- Physician Purchase (buy and bill)
- Specialty Pharmacy

Identify Diagnosis Details

Codes

- Determine appropriate ICD-10 diagnosis code
- HCPCS code (J-Code): J3111 (injection, romosozumab-aqqg)
- 210 mg monthly for 12 months
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DEXA results (BMD) T-score

- Original T-score
- Most recent T-score

FRAX® score 10-year fracture risk assessment (if available)

Document Treatment History

Be prepared to identify previous therapies that were tried, failed, or contraindicated, as some payers may require this. Record reasons for failure. Examples may include: gastrointestinal symptoms, no improvement or worsening of T-score, fractured on therapy, or other side effects.

Oral bisphosphonates[1]

- FOSAMAX® (alendronate sodium)

IV bisphosphonates[2]

- Reclast® (zoledronic acid)

RANK Ligand Inhibitor[2]

- Prolia® (denosumab)

Parathyroid Hormone (PTH)[3]

- TYMLOS® (abaloparatide)
- FORTEO® (teriparatide injection)

Please document other failed therapies not listed, including calcium and vitamin D

Consider the Patient's Risk Factors for Fracture and Other Considerations

Common Risk Factors for Fracture[3]

- Prior fragility fracture
- Low BMD (≤-2.5)
- Age >65 years
- Low body weight
- Long-term glucocorticoid use
- Cigarette smoking
- Immobilization
- Parental history of hip fracture
- Rheumatoid arthritis
- Excessive alcohol intake (>3 drinks/day)
- Diabetes
- Risk of falling

Very High Risk for Fracture (One is needed to be considered very high risk.)[3]

- Recent fracture (within past 12 months)
- Very high fracture probability per FRAX® (eg, >30% major osteoporotic fracture, >4.5% hip)
- Fracture while on approved therapy for osteoporosis
- Fractures while on drugs that may cause skeletal harm
- Experienced multiple fractures
- Very low T-score (eg, <-3.0)
- High risk for falls or history of injurious falls

Other Potential Considerations

- MI or stroke in the last 12 months (see EVENITY® Boxed Warning)[4]
- Recent calcium metabolic panel (CMP) results[3]
- Calcium and vitamin D supplementation[2]
- Height loss[3]
- Lack of coordination[5]
- Cognitive impairment[5]
- Gastrointestinal disorder (eg, GERD)[6]
- Impaired kidney function[3]

BMD=bone mineral density; CMP=calcium metabolic panel; DEXA=dual x-ray absorptiometry; FRAX®=Fracture Risk Assessment Tool; GERD=gastroesophageal reflux disease; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; IV=intravenous; MI=myocardial infarction; PA=prior authorization.

IMPORTANT SAFETY INFORMATION

POTENTIAL RISK OF MYOCARDIAL INFARCTION, STROKE, AND CARDIOVASCULAR DEATH

EVENITY® may increase the risk of myocardial infarction, stroke and cardiovascular death. EVENITY® should not be initiated in patients who have had a myocardial infarction or stroke within the preceding year. Consider whether the benefits outweigh the risks in patients with other cardiovascular risk factors. Monitor for signs and symptoms of myocardial infarction and stroke and instruct patients to seek prompt medical attention if symptoms occur. If a patient experiences a myocardial infarction or stroke during therapy, EVENITY® should be discontinued.

Please see additional Important Safety Information on next page.

INDICATION

EVENITY® 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.

The anabolic effect of EVENITY® wanes after 12 monthly doses of therapy. Therefore, the duration of EVENITY® use should be limited to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an antiresorptive agent should be considered.

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In a randomized controlled trial in postmenopausal women, there was a higher rate of major adverse cardiac events (MACE), a composite endpoint of cardiovascular death, nonfatal myocardial infarction and nonfatal stroke, in patients treated with EVENITY® compared to those treated with alendronate.

Contraindications: EVENITY® is contraindicated in patients with hypocalcemia. Pre-existing hypocalcemia must be corrected prior to initiating therapy with EVENITY®. EVENITY® is contraindicated in patients with a history of systemic hypersensitivity to romosozumab or to any component of the product formulation. Reactions have included angioedema, erythema multiforme, and urticaria.

Hypersensitivity: Hypersensitivity reactions, including angioedema, erythema multiforme, dermatitis, rash, and urticaria have occurred in EVENITY®-treated patients. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue further use of EVENITY®.

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Osteonecrosis of the Jaw (ONJ): ONJ, which can occur spontaneously, is generally associated with tooth extraction and/or local infection with delayed healing, and has been reported in patients receiving EVENITY®. A routine oral exam should be performed by the prescriber prior to initiation of EVENITY®. Concomitant administration of drugs associated with ONJ (chemotherapy, bisphosphonates, denosumab, angiogenesis inhibitors, and corticosteroids) may increase the risk of developing ONJ. Other risk factors for ONJ include cancer, radiotherapy, poor oral hygiene, pre-existing dental disease or infection, anemia, and coagulopathy.

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Atypical Femoral Fractures: Atypical low-energy or low trauma fractures of the femoral shaft have been reported in patients receiving EVENITY®. Causality has not been established as these fractures also occur in osteoporotic patients who have not been treated.

During EVENITY® treatment, patients should be advised to report new or unusual thigh, hip, or groin pain. Any patient who presents with thigh or groin pain should be evaluated to rule out an incomplete femur fracture. Interruption of EVENITY® therapy should be considered based on benefit-risk assessment.

Adverse Reactions: The most common adverse reactions (≥ 5%) reported with EVENITY® were arthralgia and headache.

EVENITY® is a humanized monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity.

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Please scan the QR code or visit www.evenity.com/PI for EVENITY® full Prescribing Information, including Boxed Warning and Medication Guide.

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AMGEN®

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