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

Prior Authorization Tip Sheet

Patient name: _____ **Date of service:** _____

EVENITY 210 mg monthly for 12 months

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

This PA tip sheet is intended to address fulfillment through the medical benefit. If you are completing a PA for a patient through the pharmacy benefit, please consult individual payer policies for more information.

MEDICAL BENEFIT (Part B/commercial) fulfilled through:

- ☐ Physician Purchase: Buy and Bill
- ☐ Alternate Site of Care/Injection Center
- ☐ Specialty Pharmacy (through medical benefit)*

Tip: Consider including the J-code to facilitate fulfillment through the medical benefit when using a specialty pharmacy: J-code: J3111

Identify Diagnosis Details

Select appropriate diagnosis code

- ☐ Osteoporosis w/ Fracture
- ☐ Osteoporosis w/o Fracture
- ☐ Additional diagnosis code _____
- ☐ Date of fracture _____

DXA results (BMD) T-score

- ☐ Most recent T-score _____ (if available)
- ☐ Original T-score _____

- ☐ **FRAX 10-year Major Osteoporotic Fracture risk** _____
- ☐ **FRAX 10-year Hip Fracture risk** _____

Document Treatment History[1]

- ☐ **Calcium/vitamin D supplement**

Oral/IV bisphosphonates

- ☐ FOSAMAX® (alendronate sodium)
- ☐ RECLAST® (zoledronic acid)
- ☐ Other _____

RANK ligand inhibitor

- ☐ PROLIA® (denosumab)
- ☐ Denosumab biosimilar[2]

Parathyroid hormone (PTH)

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

Please document other failed therapies not listed, including reasons for failure:

_____

_____

_____

Document the Patient's Risk Factors for Fracture and Other Considerations[1]

Risk Factors for Fracture

- ☐ Prior fragility fracture
- ☐ BMD T-score ≤ –2.5
- ☐ Age ≥ 65 years
- ☐ Low body weight
- ☐ Diabetes
- ☐ Rheumatoid arthritis
- ☐ Long-term glucocorticoid use
- ☐ Parental history of hip fracture
- ☐ Height loss
- ☐ Cigarette smoking
- ☐ Excessive alcohol intake (> 3 drinks/day)

The following may place patients at VERY high risk for fracture (per AACE Guidelines)[1]

- ☐ Recent fracture (within past 12 months)
- ☐ Very high fracture probability per FRAX® (eg, > 30% major osteoporotic fracture, > 4.5% hip fracture)
- ☐ Experienced multiple fractures
- ☐ Fracture while on approved therapy for osteoporosis or while on therapy causing skeletal harm
- ☐ Very low T-score (eg, < –3.0)
- ☐ History of falls
- ☐ High risk for falls
  - Neurologic disorders
  - Impaired vision and/or hearing
  - Medications
  - Environmental factors

*Reporting policies for discarded units for payers other than traditional fee-for-service Medicare may vary; providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifiers.

AACE=American Association of Clinical Endocrinology; BMD=bone mineral density; DXA=dual-energy x-ray absorptiometry; FRAX®=Fracture Risk Assessment Tool; IV=intravenous.

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 back.

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®.

Hypocalcemia: Hypocalcemia has occurred in patients receiving EVENITY®. Correct hypocalcemia prior to initiating EVENITY®. Monitor patients for signs and symptoms of hypocalcemia, particularly in patients with severe renal impairment or receiving dialysis. Adequately supplement patients with calcium and vitamin D while on EVENITY®.

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.

For patients requiring invasive dental procedures, clinical judgment should guide the management plan of each patient. Patients who are suspected of having or who develop ONJ should receive care by a dentist or an oral surgeon. In these patients, dental surgery to treat ONJ may exacerbate the condition. Discontinuation of EVENITY® should be considered based on benefit-risk assessment.

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.

References: 1. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists/American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis—2020 update. *Endocr Pract.* 2020;26(suppl1):1-46. **2.** UnitedHealthcare® Medicare Advantage Drug Policy. Medicare Part B Step Therapy Programs. November 1, 2025.

Please see EVENITY® full Prescribing Information, including Boxed Warning and Medication Guide.

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