
Patient Name: _____

Insurance Company: _____

Address Line 1: _____

Policy ID: _____

Address Line 2: _____

Policy Group: _____

Date of Birth: _____

(mm/dd/yyyy)

Attn: _____, _____

Dear _____,

I am writing this letter on behalf of my patient, _____.

EVENITY® (romosozumab-aqqg) 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

Based on the FDA-approved indication, I strongly believe that treatment with EVENITY® is medically necessary.

EVENITY® is medically necessary for _____ as documented by:

The latest treatment guidelines by the American Association of Clinical Endocrinologists (AACE) include EVENITY® as an initial therapy option for patients **at very high risk of fracture, which is defined as ANY of the following criteria:** Patients with a recent fracture (eg, within the past 12 months); fractures while on approved osteoporosis therapy; multiple fractures; fractures while on drugs causing skeletal harm; very low T-score (eg, <-3.0); high risk for falls or history of injurious falls; **OR** very high fracture probability by FRAX® (Fracture Risk Assessment Tool) (eg, major osteoporosis fracture >30%, hip fracture >4.5%); or other validated fracture risk algorithm.²

In summary, based on my clinical opinion, EVENITY® is medically necessary for _____.
This is fully consistent with both the FDA-approved indication and the current standards of care.

Please call my office at _____ if I can provide you with any additional information to approve my request.

Sincerely,

Please see Important Safety Information on next page.

USA-785-81341

IMPORTANT SAFETY INFORMATION

POTENTIAL RISK OF MYOCARDIAL INFARCTION, STROKE, AND CARDIOVASCULAR DEATH

EVENTITY® (romosozumab-aqqg) may increase the risk of myocardial infarction, stroke and cardiovascular death. EVENTITY® 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, EVENTITY® should be discontinued.

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 EVENTITY® compared to those treated with alendronate.

Contraindications: EVENTITY® is contraindicated in patients with hypocalcemia. Pre-existing hypocalcemia must be corrected prior to initiating therapy with EVENTITY®. EVENTITY® 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 EVENTITY®-treated patients. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue further use of EVENTITY®.

Hypocalcemia: Hypocalcemia has occurred in patients receiving EVENTITY®. Correct hypocalcemia prior to initiating EVENTITY®. 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 EVENTITY®.

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 EVENTITY®. A routine oral exam should be performed by the prescriber prior to

initiation of EVENTITY®. 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 EVENTITY® 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 EVENTITY®. Causality has not been established as these fractures also occur in osteoporotic patients who have not been treated.

During EVENTITY® 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 EVENTITY® therapy should be considered based on benefit-risk assessment.

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

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

INDICATION

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

Please see EVENTITY® full Prescribing Information, including Medication Guide.