[Note: This example letter is provided as a courtesy and not intended to be directive. Physicians should exercise medical judgment and discretion to appropriately diagnose and characterize the individual patient's medical condition. In addition, HCPs are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement. Please delete this paragraph prior to submitting your Letter of Medical Necessity.]

EVENITY® (romosozumab-aqqg) Sample Letter of Medical Necessity

Physician Letterhead

[Patient Name]

[Address Line 1]

[Address Line 2]

RE: Insurance Company: _____

Policy ID: _____

Policy Group: _____

Date of Birth: _____

[Date]

Attn [Medical/Pharmacy Director], [Department] :

Dear [Medical/Pharmacy Director] :

I am writing this letter on behalf of my patient, [Patient Name] .

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.

[If prior authorization has been submitted previously, indicate date of submission and the outcome. If applicable, insert denial reason from the insurance company.]

Based on the FDA-approved indication and results from the randomized Phase 3 head-to-head clinical trial comparing its efficacy and safety to an oral bisphosphonate found in EVENITY®'s Prescribing Information, I strongly believe that treatment with EVENITY® is medically necessary.[1]

EVENITY® is medically necessary for [Patient's Name] as documented by:

[Based on your clinical judgement, include patient's relevant medical history, including the following if appropriate:]

- **[If applicable] High risk for fracture, such as a history of osteoporotic fracture or multiple risk factors for fracture:**[1]

[Indicate if the patient has suffered from a prior osteoporotic fracture or list any risk factors for fracture.]

The current 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 (e.g., within the past 12 months); fractures while on approved osteoporosis therapy; multiple fractures; fractures while on drugs causing skeletal harm; very low T-score (e.g., <-3.0); high risk for falls or history of injurious falls; **OR** very high fracture probability by FRAX® (Fracture Risk Assessment Tool) (e.g., major osteoporosis fracture >30%, hip fracture >4.5%); or other validated fracture risk algorithm.[2]

- **[If applicable] Failed or intolerant to other available osteoporosis therapy:**[1]

[List any clinical characteristics of the patient that could inhibit their ability to receive an available osteoporosis therapy, or intolerance to treatment.]

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

Please call my office at [Office Phone Number] if I can provide you with any additional information to approve my request.

Sincerely,

[Physician's name]

[List supporting documents as appropriate: Examples of supporting documents include excerpt(s) from patient's medical record, relevant treatment guidelines, and product Prescribing Information.]

Please see Indication and Important Safety Information on next page.

This page is for your reference only. Content on this page does not need to be sent to the insurance company.

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.

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.

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.

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

References: 1. EVENITY® (romosozumab-aqqg) prescribing information, Amgen. **2.** Camacho P, 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(suppl 1):1-46.