MEDICARE HEALTH INSURANCE

DO YOU HAVE MEDICARE PATIENTS WITH POSTMENOPAUSAL OSTEOPOROSIS AT HIGH RISK FOR FRACTURE?

For demonstration purposes only; hypothetical Medicare beneficiary card and patient:

Name/Nombre

Sue Johnson

Medicare Number/Número de Medicare

0AA0-AA0-AA00

Entitled to/Con derecho a	Coverage starts/Cobertura empieza
HOSPITAL (PART A)	1-01-2024
MEDICAL (PART B)	1-01-2024

100% of Medicare Part B patients have access to EVENITY® as initial therapy[1,*]

• No step edit required • No prior authorization required

88% of Medicare Part B patients pay $0 for each dose of EVENITY®[2,†,‡]

- After deductible has been met, Medicare typically picks up 80% of office-administered products under Part B[3]
- Patients may obtain an additional insurance plan (eg, Medigap, commercial, TRICARE) to pick up the additional 20%[4,§]
- Data do not include medical benefit out-of-pocket (OOP) costs related to office visits or administration of EVENITY®. Additional insurance may require additional monthly premiums.[4] Individual OOP costs will vary

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 Important Safety Information on back page.

*All Medical Lives associated with Coverage Restriction for EVENITY® in MMIT coverage data snapshot as of January 2024 are included in this analysis.
†Amgen SupportPlus insurance verification data for January 2023 to December 2023 was analyzed to determine the OOP Distribution. EVENITY® prospective patients are only included in the analysis.
‡The co-pay may depend on coverage of additional insurance plan.
§Patients should be enrolled in Medicare Part A and Part B. Medicare patients with supplemental coverage (eg. Medigap) may require additional premiums.

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

100% of Medicare Part B patients have access to Prolia® as initial therapy[5,*]

• No step edit required • No prior authorization required

85% of Medicare Part B patients pay **$0** per syringe of Prolia®[6,†,‡]

- After deductible has been met, Medicare typically picks up 80% of office-administered products under Part B[3]
- Patients may obtain an additional insurance plan (eg, Medigap, commercial, TRICARE) to pick up the additional 20%[4,§]
- Data do not include medical benefit out-of-pocket (OOP) costs related to office visits or administration of Prolia®. Additional insurance may require additional monthly premiums.[4] Individual OOP costs will vary

Indication

Prolia is indicated for the treatment of postmenopausal women with osteoporosis 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. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral, and hip fractures.

Please see Important Safety Information on back page.

*All Medical Lives associated with Coverage Restriction for Prolia® in MMIT coverage data snapshot as of January 2024 are included in this analysis.
†Amgen SupportPlus insurance verification data for January 2023 to December 2023 was analyzed to determine the OOP Distribution. Prolia® prospective patients are only included in the analysis.
‡The co-pay may depend on coverage of additional insurance plan.
§Patients should be enrolled in Medicare Part A and Part B. Medicare patients with supplemental coverage (eg. Medigap) may require additional premiums.

prolia® (denosumab) injection

EVENITY® 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.

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

References: 1. Data on file, Amgen; [1]; 2024. **2.** Data on file, Amgen; [1]; 2023. **3.** Medicare.gov website. Medicare costs at a glance. https://www.medicare.gov/your-medicare-costs/medicare-costs-at-a-glance. Accessed February 21, 2024. **4.** Medicare.gov website. What's Medicare Supplement (Medigap)? https://www.medicare.gov/supplements-other-insurance/whats-medicare-supplement-insurance-Medigap. Accessed February 21, 2024. **5.** Data on file, Amgen; [2]; 2024. **6.** Data on file, Amgen; [2]; 2023.

Prolia® Important Safety Information

SEVERE HYPOCALCEMIA IN PATIENTS WITH ADVANCED KIDNEY DISEASE:

Patients with advanced chronic kidney disease are at greater risk of severe hypocalcemia following Prolia administration. Severe hypocalcemia resulting in hospitalization, life-threatening events and fatal cases have been reported. The presence of chronic kidney disease-mineral bone disorder (CKD-MBD) markedly increases the risk of hypocalcemia. Prior to initiating Prolia in patients with advanced chronic kidney disease, evaluate for the presence of CKD-MBD. Treatment with Prolia in these patients should be supervised by a healthcare provider with expertise in the diagnosis and management of CKD-MBD.

Contraindications: Prolia® is contraindicated in patients with hypocalcemia. Pre-existing hypocalcemia must be corrected prior to initiating Prolia®. Prolia® is contraindicated in women who are pregnant and may cause fetal harm. In women of reproductive potential, pregnancy testing should be performed prior to initiating treatment with Prolia®. Prolia® is contraindicated in patients with a history of systemic hypersensitivity to any component of the product. Reactions have included anaphylaxis, facial swelling and urticaria.

Severe Hypocalcemia and Mineral Metabolism Changes: Prolia can cause severe hypocalcemia and fatal cases have been reported. Pre-existing hypocalcemia must be corrected prior to initiating therapy with Prolia. Adequately supplement all patients with calcium and vitamin D.

In patients without advanced chronic kidney disease who are predisposed to hypocalcemia and disturbances of mineral metabolism (e.g. treatment with other calcium-lowering drugs), assess serum calcium and mineral levels (phosphorus and magnesium) 10 to 14 days after Prolia injection.

Same Active Ingredient: Prolia® contains the same active ingredient (denosumab) found in XGEVA®. Patients receiving Prolia® should not receive XGEVA®.

Hypersensitivity: Clinically significant hypersensitivity including anaphylaxis has been reported with Prolia®. Symptoms have included hypotension, dyspnea, throat tightness, facial and upper airway edema, pruritus and urticaria. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue further use of Prolia®.

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 Prolia®. An oral exam should be performed by the prescriber prior to initiation of Prolia®. A dental examination with appropriate preventive dentistry is recommended prior to treatment in patients with risk factors for ONJ such as invasive dental procedures, diagnosis of cancer, concomitant therapies (e.g. chemotherapy, corticosteroids, angiogenesis inhibitors), poor oral hygiene, and co-morbid disorders. Good oral hygiene practices should be maintained during treatment with Prolia®. The risk of ONJ may increase with duration of exposure to Prolia®.

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. Extensive dental surgery to treat ONJ may exacerbate the condition. Discontinuation of Prolia® should be considered based on individual benefit-risk assessment.

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

During Prolia® 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 Prolia® therapy should be considered, pending a risk/benefit assessment, on an individual basis.

Multiple Vertebral Fractures (MVF) Following Discontinuation of Prolia® Treatment: Following discontinuation of Prolia® treatment, fracture risk increases, including the risk of multiple vertebral fractures. New vertebral fractures occurred as early as 7 months (on average 19 months) after the last dose of Prolia®. Prior vertebral fracture was a predictor of multiple vertebral fractures after Prolia® discontinuation. Evaluate an individual's benefit/risk before initiating treatment with Prolia®. If Prolia® treatment is discontinued, patients should be transitioned to an alternative antiresorptive therapy.

Serious Infections: In a clinical trial (N = 7808), serious infections leading to hospitalization were reported more frequently in the Prolia® group than in the placebo group. Serious skin infections, as well as infections of the abdomen, urinary tract and ear, were more frequent in patients treated with Prolia®.

Endocarditis was also reported more frequently in Prolia®-treated patients. The incidence of opportunistic infections and the overall incidence of infections were similar between the treatment groups. Advise patients to seek prompt medical attention if they develop signs or symptoms of severe infection, including cellulitis.

Patients on concomitant immunosuppressant agents or with impaired immune systems may be at increased risk for serious infections. In patients who develop serious infections while on Prolia®, prescribers should assess the need for continued Prolia® therapy.

Dermatologic Adverse Reactions: Epidermal and dermal adverse events such as dermatitis, eczema and rashes occurred at a significantly higher rate with Prolia® compared to placebo. Most of these events were not specific to the injection site. Consider discontinuing Prolia® if severe symptoms develop.

Musculoskeletal Pain: Severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported in patients taking Prolia®. Consider discontinuing use if severe symptoms develop.

Suppression of Bone Turnover: Prolia® resulted in significant suppression of bone remodeling as evidenced by markers of bone turnover and bone histomorphometry. The significance of these findings and the effect of long-term treatment are unknown. Monitor patients for consequences, including ONJ, atypical fractures, and delayed fracture healing.

Adverse Reactions: The most common adverse reactions (>5% and more common than placebo) are back pain, pain in extremity, musculoskeletal pain, hypercholesterolemia, and cystitis. Pancreatitis has been reported with Prolia®.

The overall incidence of new malignancies was 4.3% in the placebo group and 4.8% in the Prolia® group. A causal relationship to drug exposure has not been established. Denosumab is a human monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity.

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

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

AMGEN®

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prolia® (denosumab) injection