

# Romosozumab-aqqg (EVENITY) Criteria for Use - Osteoporosis May 2024

**VA Pharmacy Benefits Management Services and National Formulary Committee**

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.*

The Product Information should be consulted for detailed prescribing information.

## Exclusion Criteria

If the answer to ANY item below is met, the patient should NOT receive romosozumab-aqqg.

- Patient had a myocardial infarction or stroke within the past year
- Pregnancy (known pregnancy or positive pregnancy test), or lactating
- Hypocalcemia or has a pre-existing disturbance of mineral metabolism that has not been effectively corrected or treated <sup>^1,^2</sup>
- Documentation of the need for an invasive dental procedure (e.g., tooth extraction, dental implant, and/or dental infection treatment) or recent procedure that has not fully healed
- Acute dental issue identified by history or clinician mouth examination
- Previous cumulative 12-month exposure to romosozumab

1. Examples: hypoparathyroidism, thyroid or parathyroid surgery, vitamin D deficiency, malabsorption syndromes, excision of small intestine.
2. Exception: Patients with secondary or tertiary hyperparathyroidism because of chronic kidney disease and low bone mineral density who are nonsurgical candidates.

## Inclusion Criteria

All criteria must be met to receive romosozumab <sup>^3</sup>

- Patient has a diagnosis of osteoporosis
  - Prescriber is a VA or VA Community Care endocrinologist, rheumatologist, nephrologist, geriatrician, or locally designated expert
  - Patient's total daily dietary and supplemental calcium intake is 1000 to 1200 mg/day
  - Has a 25-hydroxyvitamin D concentration >30 ng/mL or > 20 ng/ml and appropriate intake (e.g., cholecalciferol >800 international units per day)
3. Following a one-year course of romosozumab, start antiresorptive therapy to maintain bone density gains

## Additional Inclusion Criteria

One of the following must be selected to meet criteria for use

- Osteoporotic fracture and a T-score at the hip or spine of  $\leq -2.5$
- Very high fracture probability by the Fracture Risk Assessment Tool (FRAX) (e.g., major osteoporosis fracture >30%, hip fracture >4.5%)
- Patient has a T-score  $\leq -3.0$
- More than 2 osteoporotic fractures
- Continuing to lose bone mineral density or sustained an osteoporotic fracture while on approved osteoporosis therapy

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