

## Medical Policy

Evenity® (romosozumab)	
<b>MEDICAL POLICY NUMBER</b>	Med_Clin_Ops_051
<b>CURRENT VERSION EFFECTIVE DATE</b>	January 1, 2024
<b>APPLICABLE PRODUCT AND MARKET</b>	Individual Family Plan: All Plans Small Group: All Plans Medicare Advantage: All Plans

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at <http://www.cms.gov> for additional information.

Brand New Day/Central Health Medicare Plan medical policies address technology assessment of new and emerging treatments, devices, drugs, etc. They are developed to assist in administering plan benefits and do not constitute an offer of coverage nor medical advice. Brand New Day/Central Health Medicare Plan medical policies contain only a partial, general description of plan or program benefits and do not constitute a contract. Brand New Day/Central Health Medicare Plan does not provide health care services and, therefore, cannot guarantee any results or outcomes. Treating providers are solely responsible for medical advice and treatment of members. Our medical policies are updated based on changes in the evidence and healthcare coding and therefore are subject to change without notice. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). MCG™ and Care Guidelines® are trademarks of MCG Health, LLC (MCG).

## POLICY/CRITERIA

### Prior Authorization and Medical Review is required.

Coverage for Evenity will be provided for 12 months and may **NOT** be renewed.

1. Patient has a diagnosis of postmenopausal osteoporosis; **AND**
2. Patient meets one of the following criteria:
  - a. BMD T-score  $\leq$ -2.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site); **OR**
  - b. Patient has a history of one of the following resulting from minimal trauma:
    - i. Vertebral compression fracture
    - ii. Fracture of the hip
    - iii. Fracture of the distal radius
    - iv. Fracture of the pelvis
    - v. Fracture of the proximal humerus; **OR**
  - c. **Both** of the following:
    - i. BMD T-score between -1 and -2.5 (BMD T-score greater than -2.5 and

### Medical Policy

less than or equal to -1) based on BMD measurements from lumbar spine

(at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site); **AND**

- ii. **One** of the following:
  - 1. FRAX 10-year fracture probabilities: major osteoporotic fracture at 20% or more
  - 2. FRAX 10-year fracture probabilities: hip fracture at 3% or more;**AND**
- iii. History of failure, contraindication, or intolerance to oral or intravenous bisphosphonate therapy.

### LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value
2. Patients with hypocalcemia.
3. Coadministration with any of the following:
  - a. Parathyroid hormone analogs (e.g., Forteo, Tymlos)
  - b. RANK ligand inhibitors (e.g., Prolia, Xgeva)

### BACKGROUND

Evenity® (romosozumab) is a parenteral humanized IgG2 monoclonal antibody and sclerostin inhibitor indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, which is 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. Romosozumab has a dual effect of increasing bone formation and, to a lesser extent, decreasing bone resorption.

### DEFINITIONS

1. EVENITY (romosozumab-aqqg) injection, for subcutaneous use. Initial U.S. Approval: 2019
  - a. EVENITY (romosozumab-aqqg) injection is supplied as a sterile, preservative-free, clear to opalescent, colorless to light yellow solution for subcutaneous injection in a single-use prefilled syringe.
  - b. Two 105 mg/1.17 mL single use prefilled syringes are required to administer the recommended 210 mg dose of EVENITY
  - c. Each single-use prefilled syringe delivers 1.17 mL of solution containing 105 mg of romosozumab-aqqg, acetate

### CODING

Applicable NDC Codes	
55513-0880-xx	Romosozumab-aqqg 105 mg per 1.17 mL Subcutaneous Solution Prefilled Syringe

### Evenity

Med\_Clin\_Ops\_051

## Medical Policy

### Applicable Procedure Code

J3111	Injection, romosozumab-aqqg, 1 mg
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### Applicable ICD-10 Codes

M80.00XA - M80.08XS	Age-related osteoporosis with current pathological fracture
M81.0	Age-related osteoporosis without current pathological fracture

## EVIDENCE BASED REFERENCES

1. Evenity™ injection for subcutaneous use [prescribing information]. Thousand Oaks, CA: Amgen; April 2019.

## POLICY HISTORY

Original Effective Date	May 24, 2021
Revised Date	<p>November 1, 2021– no changes made.</p> <p>February 22, 2022 – Annual review – no changes made.</p> <p>February 28, 2023 – Annual Review and approval (no policy revisions made)</p> <p>March 1, 2023 – Adopted by MA UM Committee (no policy revisions made)</p> <p>January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)</p>

Approved by Pharmacy and Therapeutics 2/28/23