Medical Policy:

Evenity® (romosozumab) Subcutaneous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.195	April 11, 2025	

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

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.

Length of Authorization

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

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

210 mg every (1) month (210 billable units every month)

Guideline

I. Initial Approval Criteria

Evenity *may be considered medically necessary if one of the below conditions are met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

1. Osteoporosis Treatment

Evenity is medically necessary when **ALL** of the following criteria are met:

- **A.** Diagnosis of postmenopausal osteoporosis; **AND**
- **B.** Patient must be at high risk for fracture; **AND**
  Note: high risk for fractures include, but are not limited to, one or more of the following: History of an osteoporotic fracture as an adult, parental history of hip fracture, lLow BMI, Rheumatoid arthritis, Alcohol intake (3 or more drinks per day), current smoking, history of oral glucocorticoids ≥ 5mg/d of prednisone (or equivalent) for > 3 months (ever)
- **C.** Patient has **ONE** of the following: (i, ii, **or** iii)
  - **i.** Hip/femur DXA (femoral neck or total hip) or lumbar spine T-score ≤-2.5 and/or forearm DXA at the 33% (one-third) radius site; **OR**
  - **ii.** History of fragility fracture to the hip or spine, regardless of T-score; OR
  - **iii.** T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥ 20% or hip fracture ≥ 3%; **AND**
    - **a.** History of fracture pf proximal humerus, pelvis, or distal forearm; **OR**
    - **b.** FRAX 10-year probability for major fracture ≥ 20% or hip fracture ≥ 3% **AND**
- D. Patient has **ONE** of the following:
  - i. Documented treatment failure or ineffective response± to a minimum (12) month trial on previous therapy with bisphosphonates (oral or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid; **OR**
  - ii. Patient has a documented contraindication or intolerance to **BOTH** oral bisphosphonates **AND** intravenous (IV) bisphosphonates such as alendronate, risedronate, ibandronate, or zoledronic acid; **AND**
- E. Patient has **ONE** of the following:
  - i. Documented treatment failure or ineffective response± to a minimum (12) month trial on previous therapy with RANKL-blocking agents (such as denosumab, etc.); **OR**
  - ii. Patient has a documented contraindication or intolerance to RANKL-blocking agents (such as denosumab, etc)
- F. Patient is not receiving Evenity in combination with any of the following:
  - i. Parathyroid hormone analogs (e.g., Forteo, Tymlos)
  - ii. RANK ligand inhibitors (e.g., Prolia, Xgeva)

Limitations/Exclusions

Evenity is not considered medically necessary for when any of the following selection criteria is met:

1. The patient has had an MI or stroke within the previous year
2. The patient has uncorrected hypocalcemia

Dosage/Administration

Indication	Dose
Osteoporosis	Administer 210 mg subcutaneously (as two separate subcutaneous injections of 105 mg each) by a health care provider every month for a total of 12* monthly doses.

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Applicable Procedure Codes

Code	Description
J3111	Effective 10/1/19, Injection, romosozumab-aqqg, 1 mg

Applicable NDCs

Code	Description
55513-0880-xx	Romosozumab-aqqg 105 mg per 1.17 mL Subcutaneous Solution Prefilled Syringe

ICD-10 Diagnoses

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

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	4/11/2025	Annual Review: Updated criteria to include specific fracture history and score requirements.
EmblemHealth & ConnectiCare	3/12/2024	Annual Review: Initial Criteria: Osteoporosis: Added: "Patient must be at high risk for fracture; AND *Note high risk for fractures include, but are not limited to, one or more of the following: History of an osteoporotic fracture as an adult, parental history of hip fracture, lLow BMI, Rheumatoid arthritis, Alcohol intake (3 or more drinks per day), current smoking, history of oral glucocorticoids > 5mg/d of prednisone (or equivalent) for > 3 months (ever)*Patient has ONE of the following: i, ii, or iii Hip/femur DXA (femoral neck or total hip) or lumbar spine T-score ≤-2.5 and/or forearm DXA at the 33% (one-third) radius site; OR T-score ≤-1 or low bone mass and a history of fragility fracture to the hip or spine; OR T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥ 20% or hip fracture ≥ 3%; AND" Removed: "BMD T-score ≤-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 History of one of the following resulting from minimal trauma: Vertebral compression, fracture, Fracture of the hip, Fracture of the distal radius, Fracture of the pelvis, Fracture of the proximal humerus; OR Both of the following: BMD T-score between -1 and -2.5 (BMD T-score greater than-2.5 and less than or equal to -1) based on BMD measurements from lumber spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site); AND ONE of the following: FRAX 10-year fracture probabilities: major osteoporotic fracture at 20% or more FRAX 10-year fracture probabilities: hip fracture at 3% or more; AND" Added: "Patient has ONE of the following: Documented treatment failure or ineffective response± to a minimum (12) month trial on previous therapy with bisphosphonates (oral or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid; OR Patient has a documented contraindication* or intolerance to BOTH oral bisphosphonates AND intravenous (IV) bisphosphonates such as alendronate, risedronate, ibandronate, or zoledronic acid; AND"

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		Removed: “History of failure, contraindication, or intolerance to oral or intravenous bisphosphonate therapy; AND” Added: “Patient has ONE of the following: Documented treatment failure or ineffective response± to a minimum (12) month trial on previous therapy with RANKL-blocking agents such as denosumab, etc.; OR Patient has a documented contraindication* or intolerance to RANKL-blocking agents such as denosumab, etc” Removed: “Evenity dosing is in accordance with the United States Food and Drug Administration approved labeling: 210mg once monthly; AND Authorization is for no more than 12 months. (already contained elsewhere in policy)”
EmblemHealth & ConnectiCare	7/3/2023	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	6/14/2022	Transferred policy to new template.
EmblemHealth & ConnectiCare	8/15/2019	Removed J3590, Added New code J3111, effective 10/1/19.

References

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