Romosozumab-AQQG (Evenity®)

NDC CODE(S) 55513-0880-XX EVENITY 105MG/1.17ML Solution (AMGEN)

DESCRIPTION

Romosozumab-aqqg is a humanized monoclonal antibody (IgG2) which binds to and inhibits sclerostin, a regulatory factor in bone metabolism. Through sclerostin inhibition, bone formation is increased, and, to a lesser extent, bone resorption is decreased by the stimulation of osteoblastic activity. This results in increased trabecular and cortical bone mass and improved bone structure and strength.

POLICY

- Romosozumab-aqqg for the treatment of osteoporosis in postmenopausal women is considered ***medically necessary*** if the medical appropriateness criteria are met **(See Medical Appropriateness below.)**

- Romosozumab-aqqg for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL CRITERIA

- Patient is at least 18 years of age; **AND**

Universal Criteria

- Confirmation patient is receiving calcium and Vitamin D supplementation if dietary intake is inadequate; **AND**
- Patient must not have hypocalcemia; **AND**
- Patient has not had a myocardial infarction or stroke within the preceding year *(Note: in patients with other cardiovascular disease and/or risk factors, consider whether benefits of therapy outweigh the risks);* **AND**

Osteoporosis in Women

- Patient must be at a high risk for fracture**; **AND**
- Patient must be post-menopausal; **AND**
- Patient has a documented diagnosis of osteoporosis indicated by one or more of the following:
  - Hip/femur DXA (femoral neck or total hip) or lumbar spine T-score ≤-2.5 and/or forearm DXA 33% (one-third) of the radius; **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**
- §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**
- §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.

§ Patients with extremely low BMD (T<-3.5) or a T<-2.5 with a history of fragility fractures are not subject to prior trial and failure requirements with bisphosphonates and/or denosumab

±Ineffective response is defined as one or more of the following:
– Decrease in T-score in comparison with baseline T-score from DXA scan – Patient has a new fracture while on bisphosphonate therapy
****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 – Low BMI – Rheumatoid arthritis – Alcohol intake (3 or more drinks per day) – Current smoking – History of oral glucocorticoids ≥5 mg/d of prednisone (or equivalent) for >3 months ever)
***Examples of contraindications to oral bisphosphonate therapy include the following:**
– Documented inability to sit or stand upright for at least 30 minutes – Documented pre-existing gastrointestinal disorder such as inability to swallow, Barrett's esophagus, esophageal stricture, dysmotility, or achalasia
***Examples of contraindications to injectable bisphosphonate therapy include the following:**
– Documented pre-existing hypocalcemia and disturbances of mineral metabolism – Documented pre-existing renal insufficiency defined as creatinine clearance < 35 mL/min
***Examples of contraindications to *RANKL*-blocking therapy include the following:**
– Documented pre-existing hypocalcemia and disturbances of mineral metabolism – Documented hypersensitivity to the active ingredient or its excipients

RENEWAL CRITERIA

Coverage may NOT be renewed.

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.
**Note: 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.*	

LENGTH OF AUTHORIZATION

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

DOSING LIMITS

Max Units (per dose and over time) [HCPCS Unit]:

- 210 billable units every month

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

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EFFECTIVE DATE 8/31/2021

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