

Policy: MBP 202.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Evenity (romosozumab-aqqg)

I. Policy:

Evenity (romosozumab-aqqg)

II. Purpose/Objective:

To provide a policy of coverage regarding Evenity (romosozumab-aqqg)

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:

Evenity (romosozumab-aqqg) is a sclerostin inhibitor monoclonal antibody that inhibits sclerostin, a regulatory factor in bone metabolism that inhibits Wnt/Beta-catenin signaling pathway regulating bone growth; romosozumab increases bone formation and to a lesser extent, decreases bone resorption.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Evenity (romosozumab-aqqg) will be considered medically necessary for the commercial, exchange, CHIP, and Medicare lines of business when ALL of the following criteria are met:

- Medical record documentation that Evenity is prescribed by a rheumatologist or endocrinologist **AND**
- Medical record documentation that the patient has not had a myocardial infarction or stroke within the past 12 months **AND**
- Medical record documentation of a diagnosis of postmenopausal osteoporosis **AND**
- Medical record documentation that the member has not previously received greater than or equal to 12 monthly doses of Evenity **AND**
- Medical record documentation that the patient is at high-risk of a fracture, determined by the presence of **ONE** or more of the following:
 - Previous osteoporotic fracture **OR**
 - Spine or hip DXA T-Score of -2.5 or below **OR**
 - FRAX calculation of the 10-year hip fracture risk of 3% or greater **OR**
 - FRAX calculation of the 10-year risk of major osteoporotic fractures of 20% or greater **OR**
 - Medical record documentation that the patient has failed or is intolerant to at least one prior osteoporosis therapy

QUANTITY LIMITS: 12 visits over 12 months (Facets RX count: 2520)

AUTHORIZATION DURATION: Approval will be for 12 months, or less if there is medical record documentation of a previous incomplete course of therapy with Evenity.

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 anti-resorptive agent should be considered.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Evenity [prescribing information]. Thousand Oaks, CA: Amgen Inc; April 2020.
2. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists/American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis-2020 update. Endocr Pract. 2020;26(suppl 1):1-46 [cited 2023 Dec 26]. Available from: <https://www.sciencedirect.com/science/article/pii/S1530891X20428277>

This policy will be revised as necessary and reviewed no less than annually.

Devised: 9/17/19

Revised: 8/22/23 (LOB carve out, Medicaid business segment, added Facets count), 12/29/23 (references added)

Reviewed: 8/26/20, 8/23/21, 8/23/22, 8/19/24

MA UM Committee approval: 12/31/23