MEMORIAL HERMANN HEALTH SYSTEM
MEMORIAL HERMANN HEALTH PLAN HOLDINGS, LLC
POLICY

POLICY TITLE:	MHHP MEDM-MA EVE-012 Evenity (Romosozumab-aqqg) Coverage Criteria
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POLICY PURPOSE

This policy outlines the criteria and processes governing Evenity (Romosozumab-aqqg) access under Medicare Part B coverage to ensure appropriate utilization for the treatment of osteoporosis in postmenopausal women at high risk for fracture. This is defined as a history of osteoporotic fracture, multiple risk factors for fracture, or failure or intolerance to other available osteoporosis therapy.

DEFINITIONS

Bone Mineral Density (BMD): A measure of the amount of minerals (mostly calcium and phosphorous) contained in a certain volume of bone. Bone mineral density measurements are used to diagnose osteoporosis (a condition marked by decreased bone mass), to see how well osteoporosis treatments are working, and to predict how likely the bones are to break. Low bone mineral density can occur in patients treated for cancer. Also called BMD, bone density, and bone mass.

Centers for Medicare & Medicaid (CMS): A federal agency within the U.S. Department of Health and Human Services that administers Medicare, Medicaid, and the Children's Health Insurance Program (CHIP), as well as the Health Insurance Marketplace.

Federal Drug Administration (FDA) a U.S. government agency responsible for protecting public health by ensuring the safety, efficacy, and security of human and veterinary drugs, medical devices, food, cosmetics, tobacco products, and radiation-emitting electronic products.

High risk for fracture: Includes history of:

- Osteoporotic fracture,
- Multiple clinical risk factors,
- T-score ≤ –2.5, or
- T-score between –1.0 and –2.5 with high FRAX 1-year risk score of >3% for hip fracture or >/= 20% for major osteoporotic fracture, or
- History of fragility fracture

Local Coverage Determination (LCD): a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis under such parts, in accordance with section 1862(a)(1)(A).

National Coverage Determination (NCD): A nationwide decision on whether Medicare will pay for a service.

Osteoporosis: a skeletal disorder characterized by compromised bone strength predisposing to an increased risk of fracture.

Post menopause: the time after which a woman has been without a menstrual period for 12 months.

SCOPE:

This policy applies to Memorial Hermann Health Plan Holdings, LLC. Applies to all Medicare Advantage covered members who are seeking access to Evenity (romosozumab-aqqg).

POLICY STATEMENT

Evenity (romosozumab-aqqg) is a humanized monoclonal antibody that works by inhibiting sclerostin, leading to increased bone formation and decreased bone resorption. It is FDA-approved for the treatment of osteoporosis in postmenopausal women at high risk for fracture, including those with a history of osteoporotic fracture, multiple risk factors for fracture, or those who have failed or are intolerant to other available osteoporosis therapies.

Per FDA guidance, the anabolic effect of Evenity (Romosozumab-aqqg) wanes after 12 monthly doses of therapy. The duration of Evenity should be limited to 12 monthly doses. Evenity may be approved for up to 12 monthly doses.

For Medicare Advantage members, National and Local Coverage Determinations is applied to Part B (medical benefit) drug requests when applicable. This policy will only be used in the absence of applicable CMS NCD or LCD.

Use of Evenity (romosozumab-aqqg) for any non-FDA-approved indications is not covered under this policy. A provider may request Evenity (romosozumab-aqqg) for other indications other than those listed in this policy; however, the request must include a medical necessity statement and strong evidence from Medicare approved compendia. It must also meet criteria under MHHP's Off Label use policy.

Initial Approval Criteria

Evenity (Romosozumab-aqqg) requires prior authorization and is considered medically necessary when the following are met:

1. The patient is a postmenopausal female; **AND**
2. The patient has a diagnosis of osteoporosis; **AND**
   One of the following:
   a. **Patients have a documented history of failure, intolerance or contraindication to an oral or intravenous bisphosphonate product and Prolia (Denosumab) therapy (***Examples of failure/inadequate response include: osteoporotic or fragility fracture while receiving bisphosphonate therapy, ongoing and significant loss of BMD, or lack of a BMD increase)* **OR**
   b. The patient has a high risk for fracture, defined as one or more of the following:
      a. A history of osteoporotic fracture (within the past 12 months);
      b. Bone Mineral Density (BMD) T scores at hip or spine ≤ -3.0 or ≤-2.5 **and** major osteoporotic fracture; **AND**
3. The patient has not received more than 12 monthly doses of Evenity; **AND**
4. The patient has not had a myocardial infarction or stroke within the past year; **and**
5. The dosing is in accordance with the United States Food and Drug Administration (FDA) approved labeling; **AND**
6. There is no concurrent Use with other medications for Osteoporosis.

Continuation Therapy Criteria

1. The patient has not completed 12 total monthly doses in their lifetime; **and**
2. There is no new occurrence of myocardial infarction or stroke; **and**
3. There is evidence in the clinical documentation of clinical benefit as evidenced by stability or improvement in bone mineral density.

Note: The continued use of Evenity (Romosozumab-aqqg) beyond 12 months is unproven and not medically necessary as there are no clinical trials demonstrating benefit beyond 12 months.

Limitations and Exclusions:

Evenity (Romosozumab-aqqg) is not covered for the following indications:

1. Osteoporosis in premenopausal women or men
2. Bone loss due to glucocorticoid therapy;
3. Bone loss related to rare bone disorders (e.g., osteogenesis imperfecta, Hajdu-Cheney syndrome);
4. Non-osteoporotic fracture prevention or healing.

PROCEDURE

General Requirements

Documentation such as medical records or supporting notes that clearly indicate evidence of osteoporosis must accompany the prior authorization (organization determination) request.

A determination and written notice of Memorial Hermann Health Plan's determination will be rendered within applicable regulatory timeframes. Written notification will outline appeal's rights.

RELATED DOCUMENTS

MHHP MEDM-MA 002 - Expedited Organization Determinations
MHHP MEDM-MA 003 - Standard Organization Determinations
MHHP MEDM-MA 008 - Off Label Drugs

REFERENCES

Amgen Inc. (2019). *EVENITY (romosozumab-aqqg) injection, for subcutaneous use: Prescribing information*. U.S. Food and Drug Administration. https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761062s000lbl.pdf

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