Reference number
2920-A

STANDARD MEDICARE PART B MANAGEMENT

EVENITY (romosozumab-aqqg)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Evenity is indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, 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.

Limitations of Use: Limit duration of use to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

Postmenopausal osteoporosis treatment
Authorization of a total of 12 months may be granted for treatment of postmenopausal osteoporosis in members who are at high risk for fracture.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for a total of 12 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with Evenity
B. Evenity is being used to treat an indication enumerated in Section II
C. The member is receiving benefit from therapy.
D. The member has not yet received 12 months of therapy with Evenity.

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Evenity.
2. The available compendium

a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
b. Micromedex DrugDex
c. American Hospital Formulary Service- Drug Information (AHFS-DI)
d. Lexi-Drugs

3. Clinical Practice guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis
4. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Evenity are covered.

V. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for the use of Evenity in postmenopausal women with osteoporosis can be found in the guidelines from the American Association of Clinical Endocrinologists and American College of Endocrinology. Evenity, in addition to abaloparatide, denosumab, teriparatide and zoledronate should be considered for patients unable to use oral therapy and as initial therapy for patients at very high fracture risk. Treatment with Evenity should be limited to one year and treatment followed with a drug intended for long-term use (bisphosphonate, denosumab).

Support for the use of Evenity in postmenopausal women with osteoporosis can be found in the Endocrine Society guideline "Pharmacological Management of Osteoporosis in Postmenopausal Women". The guideline recommends Evenity therapy in postmenopausal women with osteoporosis at very high risk of fracture, such as those with severe osteoporosis (i.e., low T-score < −2.5 and fractures) or multiple vertebral fractures. The guideline recommends treatment for up to 1 year for the reduction of vertebral, hip, and nonvertebral fractures. The recommended dosage is 210 mg monthly by subcutaneous injection for 12 months. Women at high risk of cardiovascular disease and stroke should not be considered for Evenity pending further studies on cardiovascular risk associated with this treatment. High risk includes prior myocardial infarction or stroke. In postmenopausal women with osteoporosis who have completed a course of Evenity, the guidelines recommend treatment with antiresorptive osteoporosis therapies to maintain bone mineral density gains and reduce fracture risk.

VI. REFERENCES

1. Evenity [package insert]. Thousand Oaks, CA: Amgen; April 2020.
2. Shoback D, Rosen CJ, Black DM, Cheung AM, Murad MH, Eastell R. Pharmacological management of osteoporosis in postmenopausal women: an Endocrine Society guideline update. *J Clin Endocrinol Metab*. 2020;105(3):dgaa048. doi:10.1210/clinem/dgaa048
3. 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. doi:10.4158/GL-2020-0524SUPPL.