

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 Indications

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.

IV. REFERENCES

Evenity [package insert]. Thousand Oaks, CA: Amgen; April 2019.