BlueCross BlueShield
Federal Employee Program

EVENITY
(romosozumab-aqqg)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Evenity inhibits the action of sclerostin, a regulatory factor in bone metabolism. Evenity increases bone formation and, to a lesser extent, decreases bone resorption. Animal studies showed that Evenity stimulates new bone formation on trabecular and cortical bone surfaces by stimulating osteoblastic activity resulting in increases in trabecular and cortical bone mass and improvements in bone structure and length (1).

Regulatory Status

FDA-approved indications: Evenity is a sclerostin inhibitor 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 (1).

<u>Limitations of use:</u>

Limit duration of use to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered (1).

Evenity has a boxed warning regarding the potential to increase risk of myocardial infarction, stroke, and cardiovascular death. It should not be initiated in patients who have had a myocardial infarction or stroke within the preceding year. If a patient experiences a myocardial infarction or stroke during therapy, Evenity should be discontinued (1).

Pre-existing hypocalcemia must be corrected prior to initiating therapy with Evenity and patients must adequately supplement with calcium and vitamin D (1).

Evenity may increase risks for osteonecrosis of the jaw, hypocalcemia, and atypical femoral fracture (1).

The safety and effectiveness of Evenity in pediatric patients less than 18 years of age have not been established (1).

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Summary

Evenity inhibits the action of sclerostin, a regulatory factor in bone metabolism. Evenity increases bone formation and, to a lesser extent, decreases bone resorption. Animal studies showed that Evenity stimulates new bone formation on trabecular and cortical bone surfaces by stimulating osteoblastic activity resulting in increases in trabecular and cortical bone mass and improvements in bone structure and length. The safety and effectiveness of Evenity in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost effective use of Evenity while maintaining optimal therapeutic outcomes.

References

Evenity [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2024.