Pharmacy Medical Necessity Guidelines:

Evenity® (romosozumab-aqqg)

Effective: November 10, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	MED	Department to Review	PRECERT /MM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

All plans except Tufts Health Public Plans:
PRECERT: 617.972.9409

Tufts Health Public Plans only:
MM: 888.415.9055

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Evenity (romosozumab-aqqg) 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.

The anabolic effect of Evenity (romosozumab-aqqg) wanes after 12 monthly doses of therapy. Therefore, the duration of treatment should be limited to 12 monthly doses. If osteoporosis remains warranted, continued therapy with an anti-resorptive agent should be considered. Evenity should be administered by a healthcare provider.

Evenity (romosozumab-aqqg) may increase the risk of myocardial infarction, stroke, and cardiovascular death. Evenity (romosozumab-aqqg) should not be initiated in patients who have had a myocardial infarction or stroke within the preceding year. The benefits and risks of treatment should be weighed in patients with other cardiovascular risk factors.

COVERAGE GUIDELINES

The plan may authorize coverage of Evenity (romosozumab-aqqg) for Members when all of the following criteria are met:

1. Documentation of one of the following:
    a. T-score of less than or equal -1.0 and greater than -2.5 and the prescriber determines the Member is at high risk for fracture
    b. T-score less than or equal to -2.5
    c. FRAX score of 10-year risk of major osteoporotic fracture ≥20% or a risk of hip fracture ≥3%
    d. One or more osteoporotic fractures

AND

2. Documentation of one of the following:
    a. The Member has had an inadequate response to, or is unable to tolerate therapy with at least one of the traditional osteoporosis treatments (e.g., alendronate, calcitonin, denosumab, ibandronate, raloxifene, zoledronic acid)
    b. The Member is new to the plan and was stabilized on Evenity (romosozumab-aqqg) prior to enrollment

LIMITATIONS

- Approval duration is limited to one year.

CODES

The following HCPCS/CPT code(s) are:

Code	Description
J3111	Injection, romosozumab-aqqg, 1 mg

REFERENCES

1. Camacho PM, Petak SM, Binkley M, et al. American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) Clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis 2016. *Endocr Pract*. 2016;22(Suppl 4): 1-42.
2. Cosman F, Crittenden DB, Adachi JD, et al. Romosozumab-aqqg treatment in postmenopausal women with osteoporosis. N Engl J Med. 2016;375(16):1532-43.
3. Evenity (romosozumab-aqqg) [prescribing information]. Thousand Oaks, CA: Amgen Inc.; 2020 April.
4. Jeremiah MR, Unwin BK, Greenwald MH, et al. Diagnosis and management of osteoporosis. Am Fam Physician. 2015;92(4):261-8.
5. National Osteoporosis Foundation. Clinician's guide to prevention and treatment of osteoporosis. 2014. URL: my.nof.org/bone-source/education/clinicians-guide-to-the-prevention-and-treatment-of-osteoporosis. Accessed 2019 July 15.
6. Saag KG, Petersen J, Brandi ML, et al. Romosozumab-aqqg or alendronate for fracture prevention in women with osteoporosis. N Engl J Med. 2017;377(15):1417-27.

APPROVAL HISTORY

August 13, 2019: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. October 1, 2019: Administrative update: Added new J Code J3111 to Medical Necessity Guideline.
2. November 10, 2020: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.