Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drug
Evenity® (romosozumab-aqqg)

Effective: January 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

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.

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

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Evenity for Members when the following criteria are met:

1. Documented diagnosis of post-menopausal osteoporosis

AND

2. Documentation of **one (1)** of the following:
   a. T-score of less than or equal to -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

3. Documentation of **one (1)** of the following:
   a. The patient has had an inadequate response to, or is unable to tolerate therapy with at least one traditional osteoporosis treatments (e.g., alendronate, abaloparatide, calcitonin, denosumab, ibandronate, raloxifene, zoledronic acid, teriparatide)
   b. The patient is new to the plan and was stabilized on Evenity prior to enrollment

Limitations

- Approval duration is limited to one year. Members new the plan stable on Evenity who meet coverage criteria will be approved for the remainder of the recommended 12 monthly doses

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	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.; 2024 October.
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 And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- November 14, 2023: Removed the Limitations Approval duration is limited to 12 once monthly doses. Each monthly dose [210 mg] consists of two separate subcutaneous injections of Evenity® (romosozumab-aqqg) (effective 12/1/23).
- November 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024.
- October 8, 2024: No changes.
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- December 2025: Evote, no changes (effective 1/1/26)

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven 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 our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update 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 Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when

applicable, and adherence to plan policies, plan procedures, and claims editing logic.