Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Evenity® (romosozumab-aqqg)

Effective: January 1, 2025

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

☒ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☒ 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

Approval of Evenity was based on results of two clinical trials with women with postmenopausal osteoporosis. In the first trial, treatment with Evenity reduced the incidence of clinical fractures compared to treatment with placebo. The endpoint was a composite endpoint of symptomatic vertebral and nonvertebral fractures. Eighty eight percent of the fractures were nonvertebral and the incidence of nonvertebral fractures was not statistically significant at 12 or 24 months. In the second trial, treatment with Evenity significantly reduced the risk of clinical fracture through the end of the primary analysis.

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,
- Multiple risk factors for fracture
- Patients who have failed or are intolerant to other available osteoporosis therapy

Clinical Guideline Coverage Criteria

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

1. Documentation the Member is a postmenopausal woman at high risk for fracture defined by **one (1)** of the following:
   a. A history of osteoporotic fracture
   b. Multiple risk factors for fracture
   c. Trial and failure or intolerance to other available osteoporosis therapies

Limitations

- Approval duration is limited to 12 monthly doses when coverage criteria are met
- Refer to the Medicare Part B Step Therapy Medical Necessity Guideline for additional requirements.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J3590	Unclassified biologics

References

1. Evenity (romosozumab-aqqg) [prescribing information]. Thousand Oaks, CA; Amgen Inc.; April 2024.
2. Cosman F, et al. Romosozumab Treatment in Postmenopausal Women with Osteoporosis. N Engl J Med. 2016 Oct 20;375(16):1532-1543.
3. Lewiekci EM, et al. One Year of Romosozumab Followed by Two Years of Denosumab Maintains Fracture Risk Reductions: Results of the FRAME Extension Study. J Bone Miner Res. 2019 Mar;34(3):419-428.
4. Camacho PM, et al. American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis—2020 Update. Endocrine Practice. 2020 May;26(1):1-46.
5. No authors listed. Management of osteoporosis in postmenopausal women: the 2021 position statement of The North American Menopause Society. Menopause. 2021 Sep 1;28(9):973-997.
6. Qaseem Amir, et al. Treatment of Low Bone Density or Osteoporosis to Prevent Fractures in Men and Women: A Clinical Practice Guideline Update from the American College of Physicians. Annals of Internal Medicine. 2017 June; 166 (11): 818-839.

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)
- September 12, 2023: Removed the Limitation Any indications other than FDA-approved indications are considered experimental or investigational and will not be approved by the health plan, and Members new the plan stable on Evenity who meet coverage criteria will be approved for the remainder of the recommended 12 monthly doses. Added the Limitation Refer to the Medicare Part B Step Therapy Medical Necessity Guideline for additional requirements. Removed the following If the Member is new to the plan and already established on Evenity (romosozumab-aqqg) treatment, the total course of treatment will not exceed a total of 12 once-monthly injections. Please include Evenity (romosozumab-aqqg) treatment history and count of remaining doses required to complete therapy. Minor wording updates to clarify coverage. Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024 (effective 1/1/2024).
- November 2023: Administrative Updates: Rebranded from Tufts Health Unify to Tufts Health One Care for 2024 and administrative update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- October 8, 2024: No changes.
- December 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 1/1/25)

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines 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.