

Effective: January 1, 2025

<p>Prior Authorization Required If <u>REQUIRED</u>, submit supporting clinical documentation pertinent to service request.</p>	<p>Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p>
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Applies to:

- CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956
- CarePartners of Connecticut Medicare Advantage PPO plans, 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,
- 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
J3111	Injection, romosozumab-aqqg, 1 mg

References

1. Evenity (romosozumab-aqqg) [prescribing information]. Thousand Oaks, CA; Amgen Inc.; April 2024.

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 (effective 1/1/2024).
 - October 8, 2024: No changes.
 - December 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 1/1/25)
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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.

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.