SmartHealth Ascension

Romosozumab

(Evenity®) J3111 (1mg)

Covered with prior authorization

Romosozumab (Evenity®) may be authorized when the following criteria are met:

Osteoporosis Treatment for a Postmenopausal Woman

- **Individual meets ONE of the following conditions:**
  - Individual has had a Bone mineral density (BMD) T-score (current or at any time in the past) at or below -2.5 at the lumbar spine, femoral neck, total hip and/or 33% (one-third) radius (wrist); **OR**
  - Individual has had an osteoporotic fracture or a fragility fracture; **OR**
  - Individual meets **BOTH** of the following:
    - Individual has low bone mass [e.g., a T-score (current or at any time in the past) between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip, and/or 33% (one third) radius (wrist)]
    - Prescriber determines that the individual is at high risk for fracture [e.g., the FRAX® (fracture risk assessment tool) 10-year probability for major osteoporotic fracture is at least 20% or the 10-year probability of hip fracture is at least 3%]; **AND**

- **Documentation of ONE of the following:**
  - Individual had failure or inadequate response to at least **ONE** of the following oral **OR** intravenous bisphosphonate products:
    - Alendronate tablets or oral solution (Fosamax)
    - Ibandronate intravenous injection or tablets (Boniva)
    - Risedronate tablets/delayed release tablets (Actonel/Atelvia)
    - Zoledronic acid intravenous infusion (Reclast)
      - ***Note:*** *Examples of failure/inadequate response include, osteoporotic or fragility fracture while receiving bisphosphonate therapy, ongoing and significant loss of BMD, or lack of a BMD increase;* **OR**
  - Individual has a contraindication per FDA label, significant intolerance, or is not a candidate for oral **OR** intravenous bisphosphonate therapy.
    - ***Note:*** *Not a candidate due to being subject to a warning per the prescribing information (labeling), having a disease characteristic, individual clinical factor[s], or other attributes/conditions or is unable to administer and requires this dosage formulation;* **OR**
  - Individual is at very high risk for fracture.
    - ***Note:*** *Examples include, recent fracture within past 12 months, fractures while on approved*

osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids), very low T-score (e.g., less than - 3.0), high risk for falls or history of injurious falls, and very high fracture probability by FRAX® (fracture risk assessment tool) (e.g., major osteoporosis fracture > 30%, hip fracture > 4.5%); **AND**

- Individual will not exceed lifetime maximum of 12 monthly doses of treatment.

Exclusion criteria:
Requests may not be approved for the following:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines.
- Hypocalcemia.
- Osteoporosis prevention.
- Concurrent use with other medications for osteoporosis.
  - **Note:** Examples include oral bisphosphonates (e.g., alendronate, risedronate, ibandronate), intravenous bisphosphonates (zoledronic acid injection [Reclast®], intravenous ibandronate), Prolia® (denosumab injection for subcutaneous use), Forteo (teriparatide injection for subcutaneous use, generic), Tymlos® (abaloparatide injection for subcutaneous use), and calcitonin nasal spray (Miacalcin®/Fortical®).
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.

Initial authorization is up to 12 months.

Reauthorization approval duration: Not applicable for continuation beyond 12 doses.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

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.

References:

1. Evenity® injection for subcutaneous use [prescribing information]. Thousand Oaks, CA: Amgen; 2020.

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.