SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Evenity® (romosozumab) **(J3111) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Optima #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Maximum Approved Dose: Two consecutive injections (105 mg each) for a total dose of 210 mg once monthly (12 visits MAX)

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Length of Authorization – Up to a total of 12 months of treatment per lifetime

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SECTION A: Diagnosis Criteria (All applicable criteria MUST be met for approval)

- ❑ Diagnosis of Osteoporosis in member over the age of 50 has been established through **ONE** of the following:
  - ❑ Presence of fragility fractures (hip or spine) in the absence of other metabolic bone disorders
  - ❑ T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip
  - ❑ T-score between -1 and -2.5 and increased risk using FRAX country-specific thresholds
  - ❑ T-score between -1 and -2.5 with a fragility fracture of the proximal humerus, pelvis, or possibly distal forearm

Definitions of bone density	
Normal	T-score > -1.0
Low bone mass (osteopenia)	T-score between -1.0 and -2.5
Osteoporosis	T-score ≤ -2.5

- ❑ Member must meet **ONE** of the following:
  - ❑ Member is postmenopausal
  - ❑ Prescriber has provided documentation that the requested agent is medically appropriate for the member's gender
- ❑ Member must meet **ONE** of the following:
  - ❑ BMD T-score ≤ -2.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site)
  - ❑ History of **ONE** of the following resulting from minimal trauma within the past 5 years:
    - ❑ Vertebral compression fracture
    - ❑ Fracture of the hip
    - ❑ Fracture of the distal radius
    - ❑ Fracture of the pelvis
    - ❑ Fracture of the proximal humerus
  - ❑ Member meets **BOTH** of the following:
    - ❑ BMD T-score between -1 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1) based on BMD measurements from lumber spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site)
    - ❑ Member has **ONE** of the following 10-year fracture probabilities:
      - ❑ FRAX 10-year fracture probabilities: major osteoporotic fracture at 20% or more
      - ❑ FRAX 10-year fracture probabilities: hip fracture at 3% or more

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SECTION B: Prerequisite Therapy of IV/oral Bisphosphanate AND Parathyroid Hormone Analog (All applicable criteria MUST be met for approval)

- ❑ Member must meet **ONE** of the following prior trial and failure requirements:
  - ❑ Member has had a 12-month minimum trial of **ONE** of the following bisphosphonates with evidence of no BMD improvement at end of trials **(medication samples/coupons/discount cards are excluded from consideration as a trial):**

❑ alendronate (generic Fosamax®)	❑ ibandronate (generic Boniva®)
❑ risedronate (generic Actonel®)	❑ zoledronic acid (generic Reclast®)

  - ❑ Member has a documented intolerance, FDA-labeled contraindication, or hypersensitivity to both an oral and IV bisphosphonate defined by **TWO** of the following **(documentation of contraindication or hypersensitivity must be submitted)**:

❑ Hypersensitivity to **TWO** bisphosphonates (one of which must be alendronate)
❑ Inability to stand or sit upright for at least 30 minutes **(applicable for oral formulation only)**
❑ Pre-existing gastrointestinal disorders (e.g., Barrett's esophagus, hypersecretory disorders, delayed esophageal emptying, atrophic gastritis)
❑ Uncorrected hypocalcemia
❑ Severe renal insufficiency as defined by creatinine clearance < 35 mL/min for alendronate agents and zoledronic acid or creatinine clearance < 30 mL/min for risedronate and ibandronate

- ❑ Member meets **ONE** of the following:
  - ❑ Member had an inadequate response to **ONE** of the following with 12-month minimum treatment and evidence of no BMD improvement at end of trials:
    - ❑ Forteo® (teriparatide) injection
    - ❑ Tymlos® (abaloparatide) injection
    - ❑ Teriperatide (recombinant) injection
  - ❑ Member has a documented intolerance, FDA labeled contraindication(s), or hypersensitivity to parathyroid hormone/analog that is **NOT** expected to occur with Evenity **(documentation of contraindication or hypersensitivity must be submitted)**

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SECTION C: Contraindications (All criteria MUST be met for approval)

- ❑ Member does **NOT** have any FDA-labeled contraindications to the requested medication
- ❑ Member does **NOT** have the presence of a thrombotic event (e.g., DVT, PE)
- ❑ Dose does **NOT** exceed FDA-approved dosing of two consecutive subcutaneous injections (105 mg each) for a total dose of 210 mg once monthly
- ❑ Individual will **NOT** use Evenity® (romosozumab-aqqg) in combination with any of the following:
  - Prolia® (denosumab)
  - Bisphosphonates
  - Evista® (raloxifene)
  - Miacalcin®/ Fortical® (calcitonin nasal spray)
  - Reclast® (zoledronic acid)
  - Forteo® (teriparatide)
  - Tymlos® (abaloparatide)
- ❑ Total duration of treatment with Evenity® (romosozumab-aqqg) has **NOT** exceeded 12 months per lifetime
- ❑ Member has **NOT** experienced heart attack, stroke, or other major cardiovascular event in the previous 12 months

Medication being provided by (check applicable box(es) below):

❑ **Physician's office** **OR** ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Optima Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Optima's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.