sSENTARA COMMUNITY PLAN
(MEDICAID)

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 1-844-305-2331**. 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**.

Denosumab Biosimilars for Osteoporosis Indications (MEDICAL)

Drug Requested: select one drug below

PREFERRED **Trial and failure of Enoby™ is required prior to the use of Jubbonti® or Stoboclo®**	
❑ **Enoby™** (denosumab-qbde) **(C9399/J3590)**	
❑ **Jubbonti®** (denosumab-bbdz) **(Q5136)**	❑ **Stoboclo®** (denosumab-bmwo) **(Q5157)**
NON-PREFERRED **Trial and failure of Enoby™ and either Jubbonti® or Stoboclo® is required prior to the use of any non-preferred denosumab biosimilar product**	
❑ **Bosaya™** (denosumab-kyqq) **(Q5161)**	❑ **Conexxence®** (denosumab-bnht) **(Q5158)**
❑ **Bildyos®** (denosumab-nxxp) **(Q5162)**	❑ **Ospomyv™** (denosumab-dssb) **(Q5159)**
❑ **Osvyrti®** (denosumab-desu) **(Q5166)**	❑ **Prolia®** (denosumab) **(J0897)**

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

Member Name: _____

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

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

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

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

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

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

Weight (if applicable): _____ **Date weight obtained:** _____

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❑ 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.

Quantity Limits:

- Osteoporosis, fracture risk reduction: 60 mg subcutaneously administered by a healthcare professional once every 6 months. Available dosage form: Single use prefilled syringe and a single use vial containing 1 mL of 60 mg/mL solution.
- 60 billable units every 6 month

GENERAL 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. **Applicable to ALL continuation of therapy requests**

- ❑ Member is 18 years of age and older
- ❑ Member is supplementing with 1,000mg of calcium and at least 400IU of vitamin D daily
- ❑ The member does not have hypocalcemia
- ❑ Confirmation that member is not pregnant if applicable
- ❑ Provider attestation that the requested product will not be used in combination with other denosumab products, bisphosphonates, romosozumab, or parathyroid hormone analogs/related peptides
- ❑ If requesting **Jubbonti® or Stoboclo®,** member must have a documented trial with an inadequate response, or intolerability to Enoby™, as indicated on the PDL:

  http://www.virginiamedicaidpharmacyservices.com/provider/preferred-drug-list/
- ❑ If requesting a **non-preferred product**, member must have a documented trial with an inadequate response, or intolerability to the preferred biosimilar denosumab products:
  - ❑ Enoby™ (denosumab-qbde) **AND**
  - ❑ Jubbonti® (denosumab-bbdz) **OR** Stoboclo® (denosumab-bmwo)

❑ Diagnosis: Osteoporosis

Initial Authorization: 6 Months

- ❑ The member is a biological female and post-menopausal
- ❑ The member is at high risk of fracture**
- ❑ Does the member have a documented diagnosis of osteoporosis indicated by one or more of the following:
  - ❑ T-score by DXA of ≤-2.5 measured at the lumbar spine, femoral neck, total hip, or forearm at the 33% (one-third) radius site; **OR**
  - ❑ History of fragility fracture to the hip or spine, regardless of T-score; **OR**

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- ❑ T-score by DXA between -1.0 and -2.5 measured at the lumbar spine, femoral neck, total hip, or forearm at the 33% (one-third) radius site; **AND**
  - History of fracture of proximal humerus, pelvis, or distal forearm; **OR**
  - FRAX 10-year probability for major fracture ≥ 20% or hip fracture ≥ 3% **AND**
- ❑ The member had a 12-month trial and failure or intolerance* to previous therapy with bisphosphonates (oral or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid

❑ **Diagnosis: Glucocorticoid – Induced Osteoporosis**

Initial Authorization: 6 Months

- ❑ The member is initiating or continuing systemic glucocorticoid therapy at a daily dosage equivalent to ≥ 2.5 mg of prednisone and is expected to remain on glucocorticoid therapy for at least 3 months
- ❑ The member is at increased risk of fracture***
- ❑ The member had a 12-month trial and failure or intolerance* to previous therapy with bisphosphonates (oral or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid

❑ **Diagnosis: Osteoporosis treatment and prevention in prostate cancer**

Initial Authorization: 6 Months

- ❑ The member is receiving androgen deprivation therapy
- ❑ The member is at high risk for fracture**

❑ **Diagnosis: Osteoporosis treatment and prevention in breast cancer**

Initial Authorization: 6 Months

- ❑ The member is receiving adjuvant aromatase inhibitor therapy for breast cancer
- ❑ The member is at high risk for fracture**

Reauthorization: 12 months. 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. **Applicable to ALL continuation of therapy requests.**

❑ **Diagnosis: Osteoporosis**

- ❑ The member continues to meet the relevant criteria identified in the initial criteria
- ❑ The member has an absence of unacceptable toxicity from the drug
- ❑ The member is being continuously monitored for response to therapy and indicates a beneficial response

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***Failed clinical trial is defined as one or more of the following**
• Decrease in T-score in comparison with baseline T-score from DXA scan • Member has a new fracture while on bisphosphonate therapy
****High risk for fractures includes, but are not limited to, one or more of the following:**
• History of osteoporotic fracture as an adult • Parental history of hip fracture • Low BMI • Rheumatoid arthritis • Alcohol intake (3 or more drinks per day) • Current smoking • History of oral glucocorticoids ≥ 5mg/d of prednisone (or equivalent) for >3 months (ever)
***Examples of contraindications to oral biphosphate therapy include the following:**
• Documented inability to sit or stand upright for at least 30 minutes • Documented pre-existing esophageal disorders such as achalasia, esophageal stricture, esophageal varices, or Barrett's esophagus • Surgical anastomoses are present in the GI tract after certain types of bariatric surgery (e.g., Roux-en-Y gastric bypass) • Documented pre-existing hypocalcemia • Documented pre-existing renal insufficiency defined as creatinine clearance < 30-35 mL/ming
***Examples of contraindications to injectable bisphosphonate therapy include the following:**
• Documented pre-existing hypocalcemia • Documented pre-existing renal insufficiency defined as creatinine clearance < 30-35 mL/min
*****Increased risk for glucocorticoid-induced osteoporosis fractures includes, but are not limited to, one or more of the following:**
• Prior osteoporotic fracture • High-dose glucocorticoid use (i.e., prednisone [or equivalent] ≥ 30 mg/d > 30 d or ≥ 5 g/yr • FRAX glucocorticoid adjusted 10-year risk of major osteoporotic fracture ≥ 20% or hip ≥ 3% • T-score by DXA of < 2.5 measured at the lumbar spine, femoral neck, total hip, or forearm at the 33% (one-third) radius site

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

❑ **Physician's office** **OR** ❑ **Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health'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.****

Approved by Pharmacy and Therapeutics Committee: 11/20/2025
REVISED/UPDATED/REFORMATTED: ~~12/12/2025 3/26/2026, 7/2/2026,~~ **7/13/2026**