

SENTARA COMMUNITY PLAN (MEDICAID)

PHARMACY 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 1-800-750-9692.** No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Denosumab Biosimilars for Osteoporosis Indications (PHARMACY)

Drug Requested: (Select one drug below)

PREFERRED	
Trial and failure of Bildyos [®] is required prior to the use of Jubbonti [®] or Stoboclo [®]	
<input type="checkbox"/> Bildyos [®] (denosumab-nxxp)	
<input type="checkbox"/> Jubbonti [®] (denosumab-bbdz)	<input type="checkbox"/> Stoboclo [®] (denosumab-bmwo)
NON-PREFERRED	
Trial and failure of Bildyos [®] and either Jubbonti [®] or Stoboclo [®] is required prior to the use of any non-preferred denosumab biosimilar product	
<input type="checkbox"/> Bosaya [™] (denosumab-kyqq)	<input type="checkbox"/> Conexxence [®] (denosumab-bnht)
<input type="checkbox"/> Enoby [™] (denosumab-qbde)	<input type="checkbox"/> Ospomyv [™] (denosumab-dssb)
<input type="checkbox"/> Prolia [®] (denosumab)	

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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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.

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 **Bildyos[®]**, 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:
 - Bildyos[®]** (denosumab-nxxp) **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**
 - 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 $\geq 20\%$ or hip fracture $\geq 3\%$ **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

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Diagnosis: Glucocorticoid – Induced Osteoporosis

Initial Authorization: 6 Months

- The member is initiating or continuing systemic glucocorticoid therapy at a daily dosage equivalent to \geq 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 $\geq 5\text{mg/d}$ 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 $< 30\text{-}35\text{ mL/min}$

***Examples of contraindications to injectable bisphosphonate therapy include the following:**

- Documented pre-existing hypocalcemia
- Documented pre-existing renal insufficiency defined as creatinine clearance $< 30\text{-}35\text{ mL/min}$

*****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] $\geq 30\text{ mg/d}$ $> 30\text{ d}$ or $\geq 5\text{ g/yr}$)
- FRAX glucocorticoid adjusted 10-year risk of major osteoporotic fracture $\geq 20\%$ or hip $\geq 3\%$
- 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 Specialty Pharmacy - PropriumRx

*****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.****