United Healthcare Community Plan

COMMONWEALTH OF VIRGINIA DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Service Authorization (SA) Form

Denosumab products

If the following information is not complete, correct, or legible, the SA process can be delayed.

Please use one form per member.

Physician Administered Drug: This form is only to be used for members obtaining the medication from a pharmacy through billing the pharmacy benefit at point-of-sale. Please reference Appendix B: Physician Administered Drug Criteria for members/providers that will obtain the medication through the medical benefit.

MEMBER INFORMATION

Last Name: _____

First Name: _____

Medicaid ID Number: _____

Date of Birth: _____

Weight in Kilograms: _____

PRESCRIBER INFORMATION

Last Name: _____

First Name: _____

NPI Number: _____

Phone Number: _____

Fax Number: _____

DRUG INFORMATION

Drug Name/Form: _____

Strength: _____

Dosing Frequency: _____

Length of Therapy: _____

Quantity per Day: _____

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

DIAGNOSIS AND MEDICAL INFORMATION

For an initial request of Prolia, Bildyos, Bosaya, Conexxence/Denosumab-bnht, Enoby, Jubbonti, Ospomyv/Denosumab-dssb, Stoboclo/Denosumab-bmwo or other densoumab products with bioequivalence to Prolia, complete the following questions to receive a 6-month approval:

1. Is the member at least 18 years of age? **AND**

   ☐ Yes ☐ No

2. Is the member supplementing with 1,000 mg of calcium and at least 400 IU of vitamin D daily? **AND**

   ☐ Yes ☐ No

3. Does the member not have hypocalcemia? **AND**

   ☐ Yes ☐ No

4. Has there been confirmation that the member is not pregnant? **AND**

   ☐ Yes ☐ No

5. Does the provider attest that the requested product will not be used in combination with other denosumab products, bisphosphonates, romosozumab, or parathyroid hormone analogs/related peptides? **AND**

   ☐ Yes ☐ No

6. For nonpreferred agents has the member had a therapeutic failure to the preferred Prolia bioequivalent? **AND**

   ☐ Yes ☐ No

7. Does the member meet criteria of ONE of the indications below? (Please complete the individual diagnosis questions and provide supporting documentation)

   ☐ Yes ☐ No

For Osteoporosis

1. If the member is a biological female, are they post-menopausal? **AND**

   ☐ Yes ☐ No ☐ The member is a biological male

2. Is the member at a high risk for fracture**? **AND**

   ☐ Yes ☐ No

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

3. Does the member have a documented diagnosis of osteoporosis indicated by one or more of the following? **OR**

   ☐ 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 ≥ 20% or hip fracture ≥ 3%;* ***AND***

4. Has 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;

   ☐ Yes ☐ No

For Glucocorticoid-Induced Osteoporosis

1. Is the member 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? **AND**

   ☐ Yes ☐ No

2. Is the member at increased risk of a fracture***?

   ☐ Yes ☐ No

3. Has 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;

   ☐ Yes ☐ No

For Osteoporosis treatment and prevention in prostate cancer

1. Is the member receiving androgen deprivation therapy? **AND**

   ☐ Yes ☐ No

2. Is the member at high risk for fracture?**

   ☐ Yes ☐ No

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

For Osteoporosis treatment and prevention in breast cancer

1. Is the member receiving adjuvant aromatase inhibitor therapy for breast cancer?

   ☐ Yes ☐ No

2. Is the member at high risk for fracture?**

   ☐ Yes ☐ No

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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 include, but are not limited to, one or more of the following:
• History of an 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 ≥5 mg/d of prednisone (or equivalent) for >3 months (ever)
*Examples of contraindications to oral bisphosphonate 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/min
*Examples of contraindications to injectable bisphosphonate therapy include the following:

◊

• Documented pre-existing hypocalcemia • Documented pre-existing renal insufficiency defined as creatinine clearance < 30-35 mL/min
***Increased risk for glucocorticoid-induced osteoporosis fracture include, 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/year) • 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

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

For an initial request of Xgeva, Aukelso, Bilprevda, Bomyntra/Denosumab-bnht, Osenvelt/Denosumab-bmwo, Wyost, Xbryk, Xtrenbo, or other densoumab products with bioequivalence to Xgeva, complete the following questions to receive a 6-month approval:

1. Will the member receive calcium and vitamin D as necessary to treat or prevent hypocalcemia? **AND**

   ☐ Yes ☐ No

2. Does the member not have hypocalcemia? **AND**

   ☐ Yes ☐ No

3. Does the provider attest that the requested product will not be used in combination with other denosumab products, bisphosphonates, romosozumab, or parathyroid hormone analogs/related peptides? **AND**

   ☐ Yes ☐ No

4. For nonpreferred agents has the member had a therapeutic failure to the preferred Xgeva bioequivalent? **AND**

   ☐ Yes ☐ No

5. Does the member meet criteria of ONE of the indications below? (Please complete the individual diagnosis questions and provide supporting documentation)

   ☐ Yes ☐ No

For prevention of skeletal-related events in patients with multiple myeloma OR bone metastases from solid tumors

1. Is the member 18 years of age or older? **AND**

   ☐ Yes ☐ No

2. Has the member had an inadequate response, contraindication* or intolerance to at least a 3 month trial of zoledronic acid? **OR**

   ☐ Yes ☐ No

3. Does the member have metastatic breast cancer, metastatic castration-resistant prostate cancer, or metastatic lung cancer (both SCLC and NSCLC)?

   ☐ Yes ☐ No

For giant cell tumor of the bone

1. Is the member 12 years of age or older and skeletally mature? **AND**

   ☐ Yes ☐ No

2. Is the disease unresectable or is surgical resection likely to result in severe morbidity?

   ☐ Yes ☐ No

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

For hypercalcemia of malignancy:

1. Is the member 18 years of age or older?

   ☐ Yes ☐ No **AND**

2. Does the member have a diagnosis of cancer? **AND**

   ☐ Yes ☐ No

3. Does the member have a diagnosis of refractory hypercalcemia of malignancy defined as an albumin-corrected calcium of >12.5 mg/dL (3.1 mmol/L) despite treatment with a minimum seven (7) day trial on previous therapy with intravenous (IV) bisphosphonates such as ibandronate or zoledronic acid? **OR**

   ☐ Yes ☐ No

4. Does the member have a documented contraindication* or intolerance to intravenous (IV) bisphosphonates such as ibandronate or zoledronic acid?

   ☐ Yes ☐ No

***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

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

For a renewal request, complete the following questions to receive a 12-month approval:

1. Does the member continue to meet the relevant criteria identified in the initial criteria? **AND**
   ☐ Yes ☐ No
2. Does the member have an absence of unacceptable toxicity from the drug? **AND**
   ☐ Yes ☐ No
3. Is the member being continuously monitored for response to therapy indicates a beneficial response?
   ☐ Yes ☐ No

Prescriber Signature (Required) **Date**

By signature, the physician confirms the above information is accurate and verifiable by member records.

Please include ALL requested information; incomplete forms will delay the SA process.

Submission of documentation does NOT guarantee coverage by the Department of Medical Assistance Services.

Fax this form to 1-866-940-7328

Pharmacy PA Call Center 1-800-310-6826