

Prior Authorization (PA) Form Denosumab

Virginia | HealthKeepers, Inc. | Anthem HealthKeepers Plus Medicaid products

If the following information is not complete, correct, or legible, the PA process can be delayed. Please use one form per member.

Member information

Last name:	First name:
Medicaid ID number:	Date of birth:
Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female	Weight in kilograms:

Prescriber information

Last name:	First name:
NPI number:	
Phone number:	Fax number:

Drug information

Drug name: _____ **Drug form:** _____

Drug 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, Conexence/Denosumab-bnht, Enoby, Jubbonti, Ospomyv/Denosumab-dssb, Stoboclo/Denosumab-bmwo or other denosumab 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

(Form continued on next page.)

Member's last name:

Member's first name:

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

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 $\geq 20\%$ or hip fracture $\geq 3\%$; 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***? AND
 Yes No

(Form continued on next page.)

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

Member's last name:

Member's first name:

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

For Osteoporosis treatment and prevention in breast cancer:

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

Yes No

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

Yes No

***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)

(Form continued on next page.)

Member's last name:

Member's first name:

***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

For an initial request of Xgeva, Aukelso, Bilprevda, Bomynta/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

(Form continued on next page.)

Member’s last name:

Member’s first name:

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

(Form continued on next page.)

Member's last name:

Member's first name:

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

For hypercalcemia of malignancy:

1. Is the member 18 years of age or older? AND
 Yes No
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

(Form continued on next page.)

Member's last name:

Member's first name:

***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

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

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 PA process.
Submission of documentation does not guarantee coverage.
The completed form may be faxed to **844-512-7020**.