



MEDICARE FORM

Prolia®, Xgeva® (denosumab) Injectable Medication Precertification Request

Page 1 of 3

(All fields must be completed and legible for precertification review.)

Virginia (HMO D-SNP)
FAX: 1-833-280-5224
PHONE: 1-855-463-0933

For other lines of business:
Please use other form.

Note: Xgeva is non-preferred.
The preferred products are
pamidronate or zoledronic acid.
Pamidronate and zoledronic acid
do not require precertification.

Please indicate: [ ] Start of treatment: Start date: \_\_\_/\_\_\_/\_\_\_ [ ] Continuation of therapy: Date of last treatment \_\_\_/\_\_\_/\_\_\_

Precertification Requested By: \_\_\_\_\_ Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

A. PATIENT INFORMATION

Form section A containing fields for Patient Information: First Name, Last Name, DOB, Address, City, State, ZIP, Home Phone, Work Phone, Cell Phone, Email, Current Weight, Height, Allergies.

B. INSURANCE INFORMATION

Form section B containing fields for Insurance Information: Aetna Member ID #, Group #, Insured, Does patient have other coverage?, If yes, provide ID#, Carrier Name, Insured.

C. PRESCRIBER INFORMATION

Form section C containing fields for Prescriber Information: First Name, Last Name, Address, City, State, ZIP, Phone, Fax, St Lic #, NPI #, DEA #, UPIN, Provider E-mail, Office Contact Name, Phone.

D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION

Form section D containing fields for Dispensing Provider/Pharmacy: Place of Administration (Self-administered, Physician's Office, Outpatient Infusion Center, Home Infusion Center, Administration code(s)), Dispensing Provider/Pharmacy (Physician's Office, Retail Pharmacy, Specialty Pharmacy, Other), Name, Address, Phone, Fax, TIN, NPI.

E. PRODUCT INFORMATION

Form section E containing fields for Product Information: Request is for (Prolia, Xgeva), Dose, Frequency, HCPCS Code.

F. DIAGNOSIS INFORMATION - Please indicate primary ICD code and specify any other where applicable.

Form section F containing fields for Diagnosis Information: Primary ICD Code, Secondary ICD Code, Other ICD Code.

G. CLINICAL INFORMATION - Required clinical information must be completed in its entirety for all precertification requests.

For All Requests: (Clinical documentation required for all requests)

Note: Xgeva is non-preferred. The preferred products are pamidronate or zoledronic acid. Pamidronate and zoledronic acid do not require precertification.

Form section G containing clinical questions: Has the patient had prior therapy with Xgeva? Has the patient had a trial and failure, intolerance, or contraindication to pamidronate or zoledronic acid? Please explain if there are any other medical reason(s) that the patient cannot use pamidronate or zoledronic acid.

Form section G containing clinical question: Please provide the patient's Bone Mineral Density (BMD) score and date obtained: T-score: \_\_\_ Date: \_\_\_/\_\_\_/\_\_\_

Form section G containing clinical question: Please indicate the location the BMD was measured: [ ] femoral neck [ ] lumbar spine [ ] total hip [ ] other: please identify: \_\_\_\_\_

Form section G containing clinical question: [ ] Yes [ ] No Is the patient receiving 1000mg of calcium and 400 international units of vitamin D daily?

Form section G containing clinical question: [ ] Yes [ ] No Does the patient have clinical evidence of uncorrected preexisting hypocalcemia?

Form section G containing clinical question: [ ] Yes [ ] No Will the patient be using denosumab in combination with intravenous bisphosphonates?

Form section G containing clinical question: [ ] Yes [ ] No Will the patient be using Prolia in combination with Xgeva?

Form section G containing clinical question: [ ] Yes [ ] No Is the patient at high risk for fractures?

Form section G containing clinical question: [ ] Yes [ ] No Has the patient had an osteoporotic fracture?

Form section G containing clinical question: [ ] Yes [ ] No Does the patient have multiple risk factors for fractures?

Form section G containing clinical question: Please explain (select all that apply): [ ] alcohol intake of 4 or more units per day [ ] parental history of hip fracture

Form section G containing clinical question: [ ] rheumatoid arthritis [ ] current tobacco smoking [ ] advanced age [ ] frailty [ ] increased fall risk

Form section G containing clinical question: [ ] glucocorticoid use [ ] none of the above

Form section G containing clinical question: [ ] Yes [ ] No Does the patient have a high FRAX fracture probability: 10-year major osteoporotic fracture risk ≥ 20% or hip fracture risk ≥ 3%?

Form section G containing clinical question: [ ] Yes [ ] No Is the patient pregnant or planning to become pregnant within 5 months of discontinuing treatment with denosumab?

Form section G containing clinical question: Please select: [ ] pregnant [ ] planning to become pregnant [ ] not pregnant or planning to become pregnant

Form section G containing clinical question: [ ] none of the above (e.g. male, not a female of childbearing potential)

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Patient First Name	Patient Last Name	Patient Phone	Patient DOB
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**G. CLINICAL INFORMATION (continued) – Required clinical information must be completed in its entirety for all precertification requests.**

**For Prolia Requests:**

**Post-menopausal osteoporosis**

Please select which of the following medication(s) was ineffective, not tolerated or contraindicated:

- Select all that apply:  Alendronate (Binosto, Fosamax or Fosamax plus D)  Etidronate disodium (Didronel)  Ibandronate (Boniva)  
 Risedronate (Actonel, Actonel with Calcium or Atelvia)  Teriparatide (Forteo, Bonsity)  Zoledronic acid (Zometa, Reclast)  
 Raloxifene (Evista)  Tamoxifen (Nolvadex/Soltamox)  Toremfifene citrate (Fareston)  
 Other: Please identify: \_\_\_\_\_

**Prevention or treatment of osteoporosis in patients receiving endocrine therapy for breast cancer**

Yes  No Is the patient receiving endocrine therapy for breast cancer?

→ Please indicate which of the following endocrine therapy (aromatase inhibitors) is being used:

- anastrozole (Arimidex)  exemestane (Aromasin)  letrozole (Femara)  Other: please identify: \_\_\_\_\_

Yes  No Is there documentation that the trial of oral and/or injectable bisphosphonates was ineffective?

→ Please identify the failure of the medication trial:  Continued bone loss  Other: please identify: \_\_\_\_\_

Bisphosphonate #1 Date range: \_\_\_\_/\_\_\_\_/\_\_\_\_ - \_\_\_\_/\_\_\_\_/\_\_\_\_

Bisphosphonate #2 Date range: \_\_\_\_/\_\_\_\_/\_\_\_\_ - \_\_\_\_/\_\_\_\_/\_\_\_\_

Yes  No Is there documented evidence that the patient has an intolerance to bisphosphonates?

Yes  No Is there documented evidence that the patient has a contraindication to bisphosphonates?

Please select which of the following bisphosphonates was ineffective, not tolerated or contraindicated:

- Select all that apply:  Alendronate (Binosto, Fosamax or Fosamax plus D)  Etidronate disodium (Didronel)  Ibandronate (Boniva)  
 Risedronate (Actonel, Actonel with Calcium or Atelvia)  Zoledronic acid (Zometa, Reclast)  
 Other: Please identify: \_\_\_\_\_

**Treatment to increase bone mass in men receiving androgen deprivation therapy**

Yes  No Does the patient have prostate cancer?

Yes  No Is the patient receiving androgen deprivation therapy?

**Treatment of bone loss in men with osteoporosis**

Yes  No Is there documentation that the patient had an oral or injectable bisphosphonate trial of at least 1-year duration?

→ Please identify the failure of the medication trial:  Continued bone loss  Other: please identify: \_\_\_\_\_

Bisphosphonate #1 Date range: \_\_\_\_/\_\_\_\_/\_\_\_\_ - \_\_\_\_/\_\_\_\_/\_\_\_\_

Bisphosphonate #2 Date range: \_\_\_\_/\_\_\_\_/\_\_\_\_ - \_\_\_\_/\_\_\_\_/\_\_\_\_

Yes  No Is there documented evidence that the patient has an intolerance to bisphosphonates?

Yes  No Is there documented evidence that the patient has a contraindication to bisphosphonates?

Please select which of the following bisphosphonates was ineffective, not tolerated or contraindicated:

- Select all that apply:  Alendronate (Binosto, Fosamax or Fosamax plus D)  Etidronate disodium (Didronel)  Ibandronate (Boniva)  
 Risedronate (Actonel, Actonel with Calcium or Atelvia)  Zoledronic acid (Zometa, Reclast)  
 Other: Please identify: \_\_\_\_\_

**Treatment of glucocorticoid-induced osteoporosis**

Yes  No Is the patient initiating or continuing systemic glucocorticoids at a daily dosage equivalent to 2.5 mg or greater of prednisone for 3 months or more?

→ Please select:  initiating systemic glucocorticoids  continuing systemic glucocorticoids

Yes  No Is the patient expected to remain on glucocorticoids for at least 6 months?

Yes  No Is there documentation that the trial of oral and/or injectable bisphosphonates was ineffective?

→ Please identify the failure of the medication trial:  Continued bone loss  Other: please identify: \_\_\_\_\_

Bisphosphonate #1 Date range: \_\_\_\_/\_\_\_\_/\_\_\_\_ - \_\_\_\_/\_\_\_\_/\_\_\_\_

Bisphosphonate #2 Date range: \_\_\_\_/\_\_\_\_/\_\_\_\_ - \_\_\_\_/\_\_\_\_/\_\_\_\_

Yes  No Is there documented evidence that the patient has an intolerance to bisphosphonates?

Yes  No Is there documented evidence that the patient has a contraindication to bisphosphonates?

Please select which of the following bisphosphonates was ineffective, not tolerated or contraindicated:

- Select all that apply:  Alendronate (Binosto, Fosamax or Fosamax plus D)  Etidronate disodium (Didronel)  Ibandronate (Boniva)  
 Risedronate (Actonel, Actonel with Calcium or Atelvia)  Zoledronic acid (Zometa, Reclast)  
 Other: Please identify: \_\_\_\_\_

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**G. CLINICAL INFORMATION (continued) - Required clinical information must be completed for ALL precertification requests.**

**For Xgeva Requests:**

**Bone metastases from solid tumors**

Please indicate which of the following pertains to the patient:  Bladder cancer  Breast cancer  Kidney cancer  Ovarian cancer  
 Non-small cell lung cancer  Prostate cancer  Thyroid cancer  
 Other: Please specify: \_\_\_\_\_

Giant cell tumor of the bone

Prevention of skeletal-related events in patients with multiple myeloma

**Treatment of hypercalcemia of malignancy**

Yes  No Has the patient been treated with intravenous bisphosphonate therapy?  
 \_\_\_\_\_> Please indicate the date range of therapy: \_\_\_\_/\_\_\_\_/\_\_\_\_ - \_\_\_\_/\_\_\_\_/\_\_\_\_

Yes  No Is the hypercalcemia of malignancy refractory to intravenous bisphosphonate therapy?

Yes  No Has the albumin-corrected serum calcium level been tested?  
 \_\_\_\_\_> Please provide the albumin-corrected serum calcium level: \_\_\_\_\_mg/dL Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

**For Continuation Requests: (Clinical documentation required for all requests)**

Yes  No Does the patient have a hypersensitivity to denosumab?

Please indicate what type of response the patient has experienced while on denosumab:  No response  Minimal response  Adequate response  
 Significant improvement

**H. ACKNOWLEDGEMENT**

**Request Completed By (Signature Required):** \_\_\_\_\_ **Date:** \_\_\_\_/\_\_\_\_/\_\_\_\_

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

The plan may request additional information or clarification, if needed, to evaluate requests.