



Prolia and biosimilars

CareFirst Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-855-330-1720.** If you have questions regarding the prior authorization, please contact CVS Caremark at **1-888-877-0518**. For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

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Patient's Name: _____ Date: _____
Patient's ID: _____ Patient's Date of Birth: _____
Physician's Name: _____
Specialty: _____ NPI#: _____
Physician Office Telephone: _____ Physician Office Fax: _____

Referring Provider Info: ☐ Same as Requesting Provider

Name: _____ NPI#: _____
Fax: _____ Phone: _____

Rendering Provider Info: ☐ Same as Referring Provider ☐ Same as Requesting Provider

Name: _____ NPI#: _____
Fax: _____ Phone: _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Required Demographic Information:

Patient Weight: _____ kg

Patient Height: _____ cm

Please indicate the place of service for the requested drug:

☐ Ambulatory Surgical ☐ Home ☐ Off Campus Outpatient Hospital
☐ On Campus Outpatient Hospital ☐ Office ☐ Pharmacy

What is the ICD-10 code? _____

What product is being requested? ☐ Prolia ☐ Bieldyos ☐ Boncresa ☐ Bosaya ☐ Conexence ☐ Enoby ☐ Jubbonti
☐ Ospomyv ☐ Osvyrti ☐ Ponlimsi ☐ Stoboclo

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

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Exception Criteria Questions:

1. The preferred products for your patient's health plan are Bildyos and Stoboclo

Can the patient's treatment be switched to one of the preferred products?

- ☐ Yes, Bildyos, *Skip to Clinical Criteria Questions*
- ☐ Yes, Stoboclo, *Skip to Clinical Criteria Questions*
- ☐ No, *Continue to Question 2*

2. Does the patient have a documented intolerable adverse event to BOTH of the preferred products (Bildyos and Stoboclo)? **ACTION REQUIRED:** *If 'yes', attach supporting chart note(s)*

- ☐ Yes, *Continue to Question 3*
- ☐ No, *Continue to Question 4*

3. Was the documented intolerable adverse event an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products)? **ACTION REQUIRED:** *If 'no', attach supporting chart note(s)*

- ☐ Yes, *Continue to Question 4*
- ☐ No, *Skip to Clinical Criteria Questions*

4. Does the patient have a documented inadequate response to BOTH of the preferred products (Bildyos and Stoboclo)?

ACTION REQUIRED: *If yes, attach supporting chart note(s)*

- ☐ Yes, *Skip to Clinical Criteria Questions*
- ☐ No, *Continue to Question 5*

5. Does the patient have a contraindication to BOTH of the preferred products (Bildyos and Stoboclo)? **ACTION REQUIRED:** *If yes, attach supporting chart note(s)*

- ☐ Yes, *Continue to Clinical Criteria Questions*
- ☐ No, *Continue to Clinical Criteria Questions*

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Criteria Questions:

1. What is the diagnosis?
☐ Postmenopausal osteoporosis, *Continue to 2*
☐ Osteoporosis in a man, *Continue to 2*
☐ Glucocorticoid-induced osteoporosis, *Continue to 2*
☐ Breast cancer, *Continue to 2*
☐ Prostate cancer, *Continue to 2*
☐ Rheumatoid arthritis, *Continue to 2*
☐ Other, please specify _____, *Continue to 2*
2. Is the request for continuation of therapy with the requested drug or a biosimilar of the requested drug?
☐ Yes, *Continue to 3*
☐ No, *Continue to 8*
3. Is the patient currently receiving the requested drug or a biosimilar of the requested drug through samples or a manufacturer's patient assistance program?
☐ Yes, *Continue to 8*
☐ No, *Continue to 4*
☐ Unknown, *Continue to 8*
4. How long has the patient been receiving the requested drug or a biosimilar of the requested drug?
☐ Less than 24 months, *Continue to 5*
☐ 24 months or more, *Continue to 6*
5. Has the patient experienced clinically significant adverse events during therapy?
☐ Yes, *No Further Questions*
☐ No, *No Further Questions*
6. Has the patient experienced clinical benefit to therapy (i.e., improvement or stabilization in T-score since the previous bone mass measurement)?
☐ Yes, *Continue to 7*
☐ No, *Continue to 7*
7. Has the patient experienced any adverse effects?
☐ Yes, *No Further Questions*
☐ No, *No Further Questions*
8. What is the diagnosis?
☐ Postmenopausal osteoporosis, *Continue to 9*
☐ Osteoporosis in a man, *Continue to 16*
☐ Glucocorticoid-induced osteoporosis, *Continue to 21*
☐ Breast cancer, *Continue to 27*
☐ Prostate cancer, *Continue to 28*
☐ Rheumatoid arthritis, *Continue to 29*
9. Does the patient have a history of fragility fractures (e.g., low trauma fracture from force similar to a fall from standing position)? ***ACTION REQUIRED:*** If Yes, attach supporting chart note(s) or medical record documentation.
☐ Yes, *No Further Questions*
☐ No, *Continue to 10*

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10. What is the patient's pre-treatment T-score? Please provide the patient's T-score prior to initiation of osteoporosis treatment. **ACTION REQUIRED:** Attach supporting chart note(s) or medical record documentation.

- ☐ -2.5 or below (e.g., -2.6, -2.7, -3) _____, *Continue to 13*
☐ Between -2.5 and -1 (e.g., -2.4, -2.3, -2) _____, *Continue to 11*
☐ -1 or above (e.g., -0.9, -0.8, -0.5) _____, *No further questions*
☐ Unknown, *No further questions*

11. What is the patient's pre-treatment Fracture Risk Assessment Tool (FRAX) score for any major fracture? Please provide the patient's FRAX score prior to initiation of osteoporosis treatment. NOTE: Calculator available at <https://fraxplus.org>. The estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture (including fractures of the spine [clinical], hip, wrist, or humerus) and 1.2 for hip fracture if glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day. **ACTION REQUIRED:** Attach supporting chart note(s) or medical record documentation.

- ☐ Greater than or equal to 20% _____, *Continue to 13*
☐ Less than 20% _____, *Continue to 12*
☐ Unknown, *Continue to 12*

12. What is the patient's pre-treatment Fracture Risk Assessment Tool (FRAX) score for hip fracture? Please provide the patient's FRAX score prior to initiation of osteoporosis treatment. NOTE: Calculator available at <https://fraxplus.org>. The estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture (including fractures of the spine [clinical], hip, wrist, or humerus) and 1.2 for hip fracture if glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day. **ACTION REQUIRED:** Attach supporting chart note(s) or medical record documentation.

- ☐ Greater than or equal to 3% _____, *Continue to 13*
☐ Less than 3% _____, *Continue to 13*
☐ Unknown, *Continue to 13*

13. Does the patient have any indicators of very high fracture risk (e.g., advanced age, frailty, glucocorticoid use, very low T-scores [-3 or below], increased fall risk)?

- ☐ Yes, *No Further Questions*
☐ No, *Continue to 14*

14. Has the patient had an inadequate response or intolerance to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], teriparatide [Forteo], abaloparatide [Tymlos])? **ACTION REQUIRED:** If Yes, attach chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

- ☐ Yes, *No Further Questions*
☐ No, *Continue to 15*

15. Has the patient had an inadequate response or intolerance to previous oral bisphosphonate therapy? **ACTION REQUIRED:** If Yes, attach chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

- ☐ Yes, *No Further Questions*
☐ No, *No Further Questions*

16. Does the patient have a history of an osteoporotic vertebral or hip fracture? **ACTION REQUIRED:** If Yes, attach supporting chart note(s) or medical record documentation.

- ☐ Yes, *No Further Questions*
☐ No, *Continue to 17*

17. What is the patient's pre-treatment T-score? Please provide the patient's T-score prior to initiation of osteoporosis

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treatment. **ACTION REQUIRED:** Attach supporting chart note(s) or medical record documentation.

- ☐ -2.5 or below (e.g., -2.6, -2.7, -3) _____, *No further questions*
- ☐ Between -2.5 and -1 (e.g., -2.4, -2.3, -2) _____, *Continue to 18*
- ☐ -1 or above (e.g., -0.9, -0.8, -0.5) _____, *Continue to 20*
- ☐ Unknown, *Continue to 20*

18. What is the patient's pre-treatment Fracture Risk Assessment Tool (FRAX) score for any major osteoporotic fracture? Please provide the patient's FRAX score prior to initiation of osteoporosis treatment. NOTE: Calculator available at <https://fraxplus.org>. The estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture (including fractures of the spine [clinical], hip, wrist, or humerus) and 1.2 for hip fracture if glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day. **ACTION REQUIRED:** Attach supporting chart note(s) or medical record documentation.

- ☐ Greater than or equal to 20% _____, *No further questions*
- ☐ Less than 20% _____, *Continue to 19*
- ☐ Unknown, *Continue to 19*

19. What is the patient's pre-treatment Fracture Risk Assessment Tool (FRAX) score for hip fracture? Please provide the patient's FRAX score prior to initiation of osteoporosis treatment. NOTE: Calculator available at <https://fraxplus.org>. The estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture (including fractures of the spine [clinical], hip, wrist, or humerus) and 1.2 for hip fracture if glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day. **ACTION REQUIRED:** Attach supporting chart note(s) or medical record documentation.

- ☐ Greater than or equal to 3% _____, *No further questions*
- ☐ Less than 3% _____, *Continue to 20*
- ☐ Unknown, *Continue to 20*

20. Has the patient had an inadequate response or intolerance to previous bisphosphonate therapy? **ACTION REQUIRED:** If Yes, attach chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

- ☐ Yes, *No Further Questions*
- ☐ No, *No Further Questions*

21. Is the patient currently receiving or will be initiating glucocorticoid therapy at a prednisone equivalent dose of greater than or equal to 2.5 mg/day for 3 months or more?

- ☐ Yes, *Continue to 22*
- ☐ No, *Continue to 22*

22. Has the patient had an inadequate response or intolerance to previous bisphosphonate therapy? **ACTION REQUIRED:** If Yes, attach chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

- ☐ Yes, *No Further Questions*
- ☐ No, *Continue to 23*

23. Does the patient have a history of a fragility fracture (e.g., low trauma fracture from force similar to a fall from standing position)? **ACTION REQUIRED:** If Yes, attach supporting chart note(s) or medical record documentation.

- ☐ Yes, *No Further Questions*
- ☐ No, *Continue to 24*

24. What is the patient's pre-treatment T-score? Please provide the patient's T-score prior to initiation of osteoporosis

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treatment. **ACTION REQUIRED:** Attach supporting chart note(s) or medical record documentation.

- ☐ -2.5 or below (e.g., -2.6, -2.7, -3) _____, *No further questions*
- ☐ Between -2.5 and -1 (e.g., -2.4, -2.3, -2) _____, *Continue to 25*
- ☐ -1 or above (e.g., -0.9, -0.8, -0.5) _____, *No further questions*
- ☐ Unknown, *No further questions*

25. What is the patient's pre-treatment Fracture Risk Assessment Tool (FRAX) score for any major fracture? Please provide the patient's FRAX score prior to initiation of osteoporosis treatment. NOTE: Calculator available at <https://fraxplus.org>. The estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture (including fractures of the spine [clinical], hip, wrist, or humerus) and 1.2 for hip fracture if glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day. **ACTION REQUIRED:** Attach supporting chart note(s) and medical record documentation.

- ☐ Greater than or equal to 20% _____, *No further questions*
- ☐ Less than 20% _____, *Continue to 26*
- ☐ Unknown, *Continue to 26*

26. What is the patient's pre-treatment Fracture Risk Assessment Tool (FRAX) score for hip fracture? Please provide the patient's FRAX score prior to initiation of osteoporosis treatment. NOTE: Calculator available at <https://fraxplus.org>. The estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture (including fractures of the spine [clinical], hip, wrist, or humerus) and 1.2 for hip fracture if glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day. **ACTION REQUIRED:** Attach supporting chart note(s) or medical record documentation.

- ☐ Greater than or equal to 3% _____, *No further questions*
- ☐ Less than 3% _____, *No further questions*
- ☐ Unknown, *No further questions*

27. Will the requested drug be used for a patient receiving adjuvant aromatase inhibition therapy for breast cancer? **ACTION REQUIRED:** If Yes, attach chart note(s), medical record documentation or claims history supporting the use of aromatase inhibition therapy.

- ☐ Yes, *No Further Questions*
- ☐ No, *No Further Questions*

28. Will the requested drug be used for a patient receiving androgen deprivation therapy for prostate cancer? **ACTION REQUIRED:** If Yes, attach chart note(s), medical record documentation or claims history supporting the use of androgen deprivation therapy.

- ☐ Yes, *No Further Questions*
- ☐ No, *No Further Questions*

29. Will the requested drug be used to inhibit progression of bone erosion for a patient with rheumatoid arthritis?

- ☐ Yes, *No Further Questions*
- ☐ No, *No Further Questions*

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Step Therapy Override 2197-D: Complete if Applicable for the state of Maryland.	Please Circle	
1. Is the requested drug being prescribed for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines)?	Yes	No
2. Does the prescribed dose and quantity fall within the FDA-approved labeling or within dosing guidelines found in the compendia of current literature?	Yes	No
3. Is the alternate drug FDA-approved for the medical condition being treated? <i>If No, No Further Questions</i>	Yes	No
4. Has the prescriber documented in the patient's chart that the requested drug was ordered for the patient in the past 180 days? <i>If No, Skip to 6</i>	Yes	No
5. Has the prescriber documented in the patient's chart that in their opinion the requested drug is effective for the patient's condition? <i>If Yes, No Further Questions</i>	Yes	No
6. Is the alternate drug contraindicated or will likely cause an adverse reaction to the patient? <i>If Yes, No Further Questions</i>	Yes	No
7. Is the alternate drug expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen? <i>If Yes, No Further Questions</i>	Yes	No
8. Is the patient stable on the requested drug for the medical condition under consideration? <i>If Yes, No Further Questions</i>	Yes	No
9. Has the patient tried a prescription drug while covered under their current policy or a previous source of coverage, that is in the same pharmacologic class or has the same mechanism of action as the alternate drug and it was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? <i>No Further Questions</i>	Yes	No

Step Therapy Override 3145-D: Complete if Applicable for the state of Virginia.	Please Circle	
1. Is the requested drug being prescribed for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines)?	Yes	No
2. Does the prescribed dose and quantity fall within the FDA-approved labeling or within dosing guidelines found in the compendia of current literature?	Yes	No
3. Is the alternate drug contraindicated? <i>If Yes, No Further Questions</i>	Yes	No
4. Is the alternate drug expected to be ineffective based on the known clinical characteristics of the patient and the prescription drug regimen? <i>If Yes, No Further Questions</i>	Yes	No
5. Has the patient tried the alternate drug while on their current or previous health benefit plan and it was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? NOTE: Pharmaceutical drug samples are not considered trial and failure of a preferred drug. <i>If Yes, No Further Questions</i>	Yes	No
6. Is the patient currently receiving a positive therapeutic outcome with the requested drug for their medical condition? <i>No Further Questions</i>	Yes	No

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X

Prescriber or Authorized Signature

Date (mm/dd/yy)

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