



Xgeva 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? _____

Which product is being requested? ☐ Xgeva ☐ Aukelso ☐ Bilprevda ☐ Bomynta ☐ Osenvelt
☐ Wyost ☐ Xbryk ☐ Xtrenbo ☐ Oziltus ☐ Jubreq

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

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CVS Caremark Specialty Pharmacy • 2211 Sanders Road NBT-6 • Northbrook, IL 60062

Phone: 1-888-877-0518 • Fax: 1-855-330-1720 • www.caremark.com

Exception Criteria Questions:

1. For MD-risk LOB only: Is the requested drug being prescribed to treat a patient with stage IV advanced, metastatic cancer with its use being consistent for an FDA-approved indication, the NCCN Drugs Biologics Compendium indication for the treatment of stage IV advanced, metastatic cancer, and/or supported by peer-reviewed medical literature?

- ☐ Yes, *skip to Clinical Criteria Questions*
☐ No, *Continue to Question 2*

2. What is the requested medication?

- ☐ Bilprevda, *skip to Clinical Criteria Questions*
☐ Osenvelt, *skip to Clinical Criteria Questions*
☐ Aukelso, *Continue to Question 3*
☐ Bomynta, *Continue to Question 3*
☐ Jubereq, *Continue to Question 3*
☐ Oziltus, *Continue to Question 3*
☐ Wyost, *Continue to Question 3*
☐ Xbryk, *Continue to Question 3*
☐ Xgeva, *Continue to Question 3*
☐ Xtrenbo, *Continue to Question 3*

3. The preferred products for your patient's health plan are Bilprevda and Osenvelt

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

- ☐ Yes, Bilprevda, *skip to Clinical Criteria Questions*
☐ Yes, Osenvelt, *skip to Clinical Criteria Questions*
☐ No, *Continue to Question 4*

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

- ☐ Yes, *Continue to Question 5*
☐ No, *Continue to Question 6*

5. 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 6*
☐ No, *skip to Clinical Criteria Questions*

6. Does the patient have a documented inadequate response to BOTH of the preferred products (Bilprevda and Osenvelt)? **ACTION REQUIRED:** *If yes, attach supporting chart note(s)*

- ☐ Yes, *skip to Clinical Criteria Questions*
☐ No, *Continue to Question 7*

7. Does the patient have a contraindication to BOTH of the preferred products (Bilprevda and Osenvelt)? **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 or indication?

- ☐ Giant cell tumor of bone, *Continue to 2*
- ☐ Prevention of skeletal-related events due to multiple myeloma or bone metastases from a solid tumor (e.g., breast cancer, non-small cell lung cancer, thyroid carcinoma, kidney cancer, prostate cancer), *Continue to 2*
- ☐ Palliative care for bone metastases from thyroid carcinoma, *Continue to 2*
- ☐ Hypercalcemia of malignancy, *Continue to 2*
- ☐ Osteopenia or osteoporosis due to systemic mastocytosis, *Continue to 2*
- ☐ Other, please specify. _____, *No further questions*

2. Is the request for continuation of therapy with the requested drug?

- ☐ Yes, *Continue to 3*
- ☐ No, *Continue to 6*

3. Is the patient diagnosed with hypercalcemia of malignancy?

- ☐ Yes, *Continue to 4*
- ☐ No, *Continue to 5*

4. Is the patient experiencing a benefit from therapy with the requested drug as evidenced by disease stability or disease improvement?

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

5. Is the patient experiencing a benefit from therapy with the requested medication as evidenced by disease stability or disease improvement?

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

6. What is the diagnosis or indication?

- ☐ Giant cell tumor of bone, *Continue to 7*
- ☐ Prevention of skeletal-related events due to multiple myeloma or bone metastases from a solid tumor (e.g., breast cancer, non-small cell lung cancer, thyroid carcinoma, kidney cancer, prostate cancer), *No further questions*
- ☐ Palliative care for bone metastases from thyroid carcinoma, *No further questions*
- ☐ Hypercalcemia of malignancy, *Continue to 8*
- ☐ Osteopenia or osteoporosis in patients with systemic mastocytosis, *Continue to 11*

7. Is a loading dose prescribed?

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

8. Is the patient's condition refractory to intravenous (IV) bisphosphonate therapy?

- ☐ Yes, *Continue to 10*
- ☐ No, *Continue to 9*

9. Is there a clinical reason to avoid treatment with an intravenous (IV) bisphosphonate (e.g., acute renal impairment, renal insufficiency [creatinine clearance less than 35 mL/min], history of intolerance to an IV bisphosphonate)?

- ☐ Yes, *Continue to 10*
- ☐ No, *Continue to 10*

10. Is a loading dose prescribed?

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

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11. Is the patient's condition refractory to bisphosphonate therapy and will be using the requested drug as second-line therapy?

☐ Yes, *No Further Questions*

☐ No, *Continue to 12*

12. Is the patient not a candidate for bisphosphonate therapy because of renal insufficiency?

☐ Yes, *No Further Questions*

☐ No, *No Further Questions*

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

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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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