

### Krystexxa

#### **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:	
Specialty:	NPI#:
Physician Office Telephone:	Physician Office Fax:
<b><u>Referring</u></b> Provider Info: Same as Requesting	ng Provider
Name:	NPI#:
Fax:	Phone:
Rendering Provider Info:	g 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

What is the ICD-10 code?

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

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### Site of Service Questions:

- A. Where will this drug be administered?
  - Ambulatory surgical, *skip to Clinical Criteria Questions*
  - □ Home infusion, *skip to Clinical CriteriaQuestions*
  - □ Off-campus Outpatient Hospital, *Continue to B*
  - □ On-campus Outpatient Hospital, *Continue to B*
  - Depresentation Physician office, *skip to Clinical Criteria Questions*
  - □ Pharmacy, *skip to Clinical Criteria Questions*
- B. Is the patient less than 14 years of age?
  □ Yes, *skip to Clinical Criteria Questions*□ No, *Continue to C*
- *C.* Is this request to continue previously established treatment with the requested medication? *ACTION REQUIRED: If No, please attach supporting clinical documentation.* 
  - □ Yes This is a continuation of an existing treatment., *Continue to D*

□ No - This is a new therapy request (patient has not received requested medication in the last 6 months)., *skip to Clinical Criteria Questions* 

D. Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (eg acetaminophen, steroids, diphenhydramine, fluids, other pre-medications or slowing of the infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion? *ACTION REQUIRED: If Yes, please attach supporting clinical documentation.* 

Yes, skip to Clinical Criteria Questions
 No, Continue to E

- E. Does the patient have laboratory confirmed anti-pegloticase antibodies? *ACTION REQUIRED: If Yes, please attach supporting clinical documentation.* 
  - Yes, skip to Clinical Criteria Questions
     No, Continue to F
- F. Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may limit the member's ability to tolerate a large volume or load or predispose the member to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment? *ACTION REQUIRED: If Yes, please attach supporting clinical documentation.*

Yes, skip to Clinical Criteria Questions
 No, Continue to G

- G. Does the patient have severe venous access issues that require the use of special interventions only available in the outpatient hospital setting? ACTION REQUIRED: If Yes, please attach supporting clinical documentation.
  □ Yes, skip to Clinical Criteria Questions
  □ No, Continue to H
- H. Does the patient have significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver? *ACTION REQUIRED: If Yes, please attach supporting clinical documentation.*□ Yes, *skip to Clinical Criteria Questions*□ No, *Continue to I*
- I. Are *all* alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) **greater than** 30 miles from the patient's home? *ACTION REQUIRED: If Yes, please attach supporting documentation.* 
  - □ Yes, continue to Clinical Criteria Questions

□ No, *continue to Clinical Criteria Questions* 

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#### **Clinical Criteria Questions:**

1. What is the diagnosis?

□ Chronic gout, *Continue to #2* 

Other\_

, Continue to #2

2. Will the requested medication be used concomitantly with oral urate-lowering therapies?

□ Yes, Continue to #3

□ No, *Continue to #3* 

3. Is the patient 18 years of age or older?

□ Yes, Continue to #4

□ No, *Continue to #4* 

4. Has the patient had at least 2 gout flares per year that were inadequately controlled by colchicine or nonsteroidal anti-inflammatory drugs (NSAIDs) at the time of initiation of treatment with the requested medication?

□ Yes, *Continue to #6* 

□ No, *Continue to #5* 

5. Has the patient had at least 1 gout tophus or gouty arthritis at the time of initiation of treatment with the requested medication?

□ Yes, *Continue to #6* 

□ No, Continue to #6

6. Has the patient had an inadequate response to at least a three-month trial of allopurinol at the medically appropriate maximum dose?

□ Yes, Continue to #10

□ No, Continue to #7

7. Does the patient have a clinical reason for not completing at least a three-month trial of allopurinol at the medically appropriate maximum dose (See Appendix A)?

□ Yes, Continue to #10

□ No, *Continue to #8* 

8. Has patient had an inadequate response to at least a three-month trial of Uloric (febuxostat) at the medically appropriate maximum dose?

 $\Box$  Yes, *Continue to #10* 

□ No, *Continue to #9* 

9. Does the patient have a clinical reason for not completing at least a three-month trial of Uloric (febuxostat) at the medically appropriate maximum dose (See Appendix A)?

□ Yes, *Continue to #10* 

 $\square$  No, *Continue to #10* 

10. Has patient had an inadequate response to at least a three-month trial of probenecid (alone or in combination with allopurinol or Uloric [febuxostat]) at the medically appropriate maximum dose?

□ Yes, *Continue to #12* 

□ No, Continue to #11

11. Does the patient have a clinical reason for not completing at least a three-month trial of probenecid (alone or in combination with allopurinol or Uloric [febuxostat]) at the medically appropriate maximum dose (See Appendix A)?

□ Yes, *Continue to #12* 

□ No, *Continue to #12* 

12. Will the requested medication be co-administered with weekly oral methotrexate and folic acid or folinic acid supplementation?

□ Yes, Continue to #14

 $\square$  No, *Continue to #13* 

13. Does the member have a contraindication to or clinical reason to avoid oral methotrexate therapy (see Appendix B)?

□ Yes, Continue to #14

 $\square$  No, *Continue to #14* 

14. Is this a request for continuation of therapy with the requested medication?

□ Yes, *Continue to #15* 

□ No, No Further Questions

15. Has the patient taken the requested medication for less than 18 months?

□ Yes, *Continue to #16* 

□ No, Continue to #16

16. Has the patient had two consecutive uric acid levels above 6 mg/dL since starting treatment with the requested medication?

□ Yes, Continue to #17

□ No, *Continue to #17* 

17. Is the patient experiencing benefit from therapy (e.g., serum uric acid levels < 6 mg/dl, reduction of tophi, reduction of symptoms and/or flares)? *ACTION REQUIRED*: If Yes, please attach chart notes or lab test results documenting a benefit from therapy (e.g., serum uric acid levels < 6 mg/dl, reduction of tophi, reduction of symptoms and/or flares)

□ Yes, Continue to #18

□ No, *Continue to #18* 

18. How many months of therapy has the patient received with the requested drug?

\_\_\_\_\_ months, No Further Questions

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# Appendix A: Clinical reasons for not completing a three-month trial with allopurinol, febuxostat, and probenecid (examples, not all inclusive):

- i. Member experienced a severe allergic reaction to the medication
- ii. Member experienced toxicity with the medication
- iii. Member could not tolerate the medication
- iv. Member's current medication regimen has a significant drug interaction
- v. Member has severe renal dysfunction (allopurinol)
- vi. Member has known blood dyscrasias or uric acid kidney stones (probenecid)
- vii. Member has renal insufficiency (i.e., glomerular filtration rate 30 mL/minute or less) (probenecid)
- viii. Member has end stage renal impairment (febuxostat)
- ix. Member has a history of CVD or a new CV event (febuxostat)

# Appendix B: Contraindications/clinical reasons to avoid oral methotrexate therapy (examples, not all inclusive):

- i. Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- ii. Breastfeeding
- iii. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
- iv. Elevated liver transaminases
- v. History of intolerance or adverse event
- vi. Hypersensitivity
- vii. Interstitial pneumonitis or clinically significant pulmonary fibrosis
- viii. Myelodysplasia
- ix. Pregnancy or currently planning pregnancy
- x. Renal impairment
- xi. Significant drug interaction

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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