Berinert

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.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

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* ❑ *Inpatient Hospital* ❑ *Off Campus Outpatient Hospital*
❑ *On Campus Outpatient Hospital* ❑ *Office* ❑ *Pharmacy*

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

Exception Criteria Questions

A. Is the product being requested for short-term preprocedural prophylaxis (i.e., prior to surgical or major dental procedures? *If Yes, skip to Clinical Criteria Questions* ❑ Yes ❑ No

B. Is the product being requested for the treatment of acute attacks of hereditary angioedema?
❑ Yes ❑ No *If No, skip to Clinical Criteria Questions*

C. The preferred product for your patient's health plan is Ruconest. Can the patient's treatment be switched to Ruconest? ❑ Yes *If Yes, Please obtain Form for preferred product and submit for corresponding PA* ❑ No

D. Has the patient tried and experienced a documented inadequate response to treatment with the preferred product (Ruconest)? **Action Required:** ***If 'Yes', attach supporting chart note(s)***
If Yes, skip to Clinical Criteria Questions ❑ Yes ❑ No

E. Has the patient tried and experienced a documented intolerable adverse event to the preferred product (Ruconest)?
Action Required: ***If 'Yes', attach supporting chart note(s).***
If Yes, skip to Clinical Criteria Questions ❑ Yes ❑ No

F. Does the patient have a documented contraindication to the preferred product (Ruconest) (i.e., a known or suspected allergy to rabbits or rabbit-derived products)? **Action Required:** ***If 'Yes', attach supporting chart note(s).***
If Yes, skip to Clinical Critera Questions ❑ Yes ❑ No

G. Is Berinert being requested for the treatment of laryngeal attacks? ❑ Yes ❑ No

Clinical Criteria Questions:

1. What is the diagnosis?
   ❑ Hereditary angioedema (HAE) with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing
   ❑ HAE with normal C1 inhibitor confirmed by laboratory testing
   ❑ Other_____

2. What is the ICD-10 code? _____

3. What is the clinical setting in which the requested medication will be used?
   ❑ Short-term preprocedural prophylaxis (i.e., prior to surgical or major dental procedures) *skip to diagnosis section*
   ❑ Acute hereditary angioedema (HAE) attacks
   ❑ Other

4. Will Berinert be used in combination with Firazyr, Kalbitor or Ruconest? ❑ Yes ❑ No

5. Has the patient previously received treatment with the requested medication?
   ❑ Yes ❑ No *If No, skip to #10*

6. Has the patient experienced a reduction in severity and/or duration of attacks when the requested medication is used to treat an acute attack? ***ACTION REQUIRED: If 'Yes', attach supporting chart note(s) demonstrating a reduction in severity and/or duration of attacks***. ❑ Yes ❑ No

7. Has the patient had more than 12 severe attacks or more than 24 days of severe symptoms in the last 12 months?
   ❑ Yes ❑ No *If No, skip to #10*

8. Has prophylactic treatment been considered*? If Yes, skip to #10* ❑ Yes ❑ No

9. Please provide a brief rationale as to why prophylactic treatment has not been considered.
   _____

10. What is the patient's body weight? _____ kg or lbs ***(Circle one)***

Complete the following section based on the patient's diagnosis, if applicable.

Section A: Hereditary Angioedema (HAE) with C1 Inhibitor Deficiency or Dysfunction Confirmed by Laboratory Testing

_____

11. Does the patient have a C4 level below the lower limit of normal as defined by the laboratory performing the test? ***ACTION REQUIRED: If 'Yes', attach laboratory test or medical record documentation confirming low C4 level.***
❑ Yes ❑ No

12. Which of the following conditions does the patient have? ***ACTION REQUIRED: For any answer, attach laboratory test or medical record documentation confirming C1 inhibitor functional and antigenic protein levels.***
❑ A C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the test
❑ A normal C1-INH antigenic level and a low C1-INH functional level (functional C1-INH less than 50% or C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test)
❑ Other _____

Section B: HAE with Normal C1 Inhibitor Confirmed by Laboratory Testing

13. Which of the following conditions does the patient have? ***ACTION REQUIRED For any answer, attach laboratory test or medical record documentation confirming C4 levels and normal C1 inhibitor. Based on the answer provided, attach genetic test or medical record documentation confirming F12, angiopoietin-1, plasminogen, or kininogen-1 (KNG1) gene mutation testing or chart notes confirming family history of angioedema.***
❑ F12, angiopoietin-1, plasminogen, or kininogen-1 (KNG1) gene mutation as confirmed by genetic testing
❑ Family history of angioedema and angioedema refractory to a trial of high-dose antihistamine (e.g. cetirizine) for at least one month
❑ Other _____

Step Therapy Override: Complete if Applicable for the state of Maryland.	Please Circle	
Is the requested drug being used to treat stage four advanced metastatic cancer?	Yes	No
Is the requested drug's use consistent with the FDA-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer and is supported by peer-reviewed medical literature?	Yes	No
Is the requested drug being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed quantity fall within the manufacturer's published dosing guidelines or within dosing guidelines found in the compendia of current literature (examples: package insert, AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Do patient chart notes document the requested drug was ordered with a paid claim at the pharmacy, the pharmacy filled the prescription and delivered to the patient or other documentation that the requested drug was prescribed for the patient in the last 180 days?	Yes	No
Has the prescriber provided proof documented in the patient chart notes that in their opinion the requested drug is effective for the patient's condition?	Yes	No

Step Therapy Override: Complete if Applicable for the state of Virginia.	Please Circle	
Is the requested drug being used for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines)?	Yes	No
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
Is the request for a brand drug that has an AB-rated generic equivalent or interchangeable biological product available?	Yes	No
Has the patient had a trial and failure of the AB-rated generic equivalent or interchangeable biological product due to an adverse event (examples: rash, nausea, vomiting, anaphylaxis) that is thought to be due to an inactive ingredient?	Yes	No
Is the preferred drug contraindicated?	Yes	No
Is the preferred drug expected to be ineffective based on the known clinical characteristics of the patient and the prescription drug regimen?	Yes	No
Has the patient tried the preferred 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?	Yes	No
Is the patient currently receiving a positive therapeutic outcome with the requested drug for their medical condition?	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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