Berinert

Prior Authorization Request

Your patient's benefit plan requires prior authorization for certain medications. In order to make appropriate medical necessity determinations, your patient's diagnosis and other clinical information is required. **Please complete the information requested on the form below and fax this form along with supporting clinical documentation to Priority Partners, toll-free at 1-866-212-4756 to initiate the review process.** If you have questions regarding the prior authorization please contact Priority Partners at 888-819-1043 Option 4**.**

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*

Drug Information:

Strength/Measure _____*Units* ❑ ml ❑ Gm ❑ mg ❑ ea ❑ Un
Directions(sig) _____*Route of administration* _____
Dosing frequency _____

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 Site of Service Questions* ❑ Yes ❑ No

B. Is the product being requested for the treatment of acute attacks of hereditary angioedema?
❑ Yes ❑ No *If No, skip to Site of Service 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. What is the patient's age?
❑ 13 years of age or older
❑ Less than 13 years of age, *Skip to Site of Service Questions*

Send completed form to: Priority Partners Fax: 1-866-212-4756

Priority Partners ● 7231 Parkway Drive Suite 100 ● Hanover, MD 21076
Phone: 888-819-1043 ● Fax: 1-866-212-4756 ● www.hopkinshealthplans.org

E. Does the patient have a documented inadequate response to treatment with the preferred product, Ruconest? **Action Required:** ***If 'Yes', attach supporting chart note(s)***
If Yes, skip to Site of Service Questions ❑ Yes ❑ No

F. Does the patient have a documented intolerable adverse event to the preferred product, Ruconest? **Action Required:** ***If 'Yes', attach supporting chart note(s).***
If Yes, skip to Site of Service Questions ❑ Yes ❑ No

G. 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 Site of Service Questions ❑ Yes ❑ No

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

Site of Service Questions:

A. Indicate the site of service requested:
❑ *Ambulatory Surgical (POS Code 24)*
❑ *Home (POS Code 12)*
❑ *Off Campus Outpatient Hospital (POS Code 19)*
❑ *On Campus Outpatient Hospital (POS Code 22)*
❑ *Office (POS Code 11)*

B. Is the patient less than 18 years of age?
❑ Yes, *skip to Clinical Criteria Questions*
❑ No

C. 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 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

D. 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

E. 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

F. 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

G. Has the patient's home been deemed not eligible or appropriate for home infusion services by a home infusion provider? ***ACTION REQUIRED: If 'Yes', please attach supporting clinical documentation.***
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

H. 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 ❑ No

Clinical Criteria Questions:

1. What is the diagnosis?

❒ Hereditary angioedema (HAE), *Continue to 2*

❒ Other, please specify. _____, *Continue to 2*

2. Will the requested drug be prescribed by or in consultation with a prescriber who specializes in the management of hereditary angioedema (HAE)?
❒ Yes, *Continue to 3*
❒ No, *Continue to 3*

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), *Continue to 4*

❒ Acute hereditary angioedema (HAE) attacks, *Continue to 7*

❒ Other, please specify. _____, *No Further Questions*

4. What is the diagnosis?
❒ Hereditary angioedema (HAE) with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing, *Continue to 5*

❒ HAE with normal C1 inhibitor confirmed by laboratory testing, *Continue to 6*

❒ Other, please specify. _____, *No Further Questions*

5. Which of the following conditions does the patient have at the time of diagnosis? ***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 ***ACTION REQUIRED****: Submit supporting documentation, Continue to 16*
❒ 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) ***ACTION REQUIRED****: Submit supporting documentation, Continue to 16*
❒ Other, please specify. _____ ***ACTION REQUIRED****: Submit supporting documentation, Continue to 16*

6. Which of the following conditions does the patient have at the time of diagnosis? ***ACTION REQUIRED***: For any answer, attach laboratory test or medical record documentation confirming normal C1 inhibitor. Based on the answer provided, attach genetic test or medical record documentation confirming F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation testing or chart notes confirming family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy.
❒ F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation as confirmed by genetic testing ***ACTION REQUIRED****: Submit supporting documentation, Continue to 16*
❒ BOTH of the following: 1) Angioedema refractory to a trial of high-dose antihistamine therapy (i.e., cetirizine at 40 mg per day or the equivalent) for at least one month AND 2) Family history of angioedema ***ACTION REQUIRED****: Submit supporting documentation, Continue to 16*
❒ Other, please specify. _____ ***ACTION REQUIRED****: Submit supporting documentation, Continue to 16*

7. What is the diagnosis?
❒ Hereditary angioedema (HAE) with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing, *Continue to 8*
❒ Hereditary angioedema (HAE) with normal C1 inhibitor confirmed by laboratory testing, *Continue to 9*
❒ Other, please specify. _____, *Continue to 10*

8. Which of the following conditions does the patient have at the time of diagnosis? ***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 ***ACTION REQUIRED****: Submit supporting documentation, Continue to 10*
❒ 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) ***ACTION REQUIRED****: Submit supporting documentation, Continue to 10*
❒ Other, please specify. _____ ***ACTION REQUIRED****: Submit supporting documentation, Continue to 10*

9. Which of the following conditions does the patient have at the time of diagnosis? ***ACTION REQUIRED***: For any answer, attach laboratory test or medical record documentation confirming normal C1 inhibitor. Based on the answer provided, attach genetic test or medical record documentation confirming F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation testing or chart notes confirming family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy.
❒ F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation as confirmed by genetic testing ***ACTION REQUIRED****: Submit supporting documentation, Continue to 10*
❒ BOTH of the following: 1) Angioedema refractory to a trial of high-dose antihistamine therapy (i.e., cetirizine at 40 mg per day or the equivalent) for at least one month AND 2) Family history of angioedema ***ACTION REQUIRED****: Submit supporting documentation, Continue to 10*
❒ Other, please specify. _____ ***ACTION REQUIRED****: Submit supporting documentation, Continue to 10*

10. Will the requested drug be used in combination with any other medication used for treatment of acute hereditary angioedema (HAE) attacks (e.g., Ruconest, Firazyr, Kalbitor)?
❒ Yes, *Continue to 11*
❒ No, *Continue to 11*

11. Has the patient previously received treatment with the requested medication?
❒ Yes, *Continue to 12*
❒ No, *Continue to 17*

12. Has the patient experienced a reduction in severity and/or duration of acute attacks? ***ACTION REQUIRED***: If Yes, attach supporting chart note(s) demonstrating a reduction in severity and/or duration of acute attacks.
❒ Yes, *Continue to 13*
❒ No, *Continue to 13*

13. Does the patient's attack frequency, attack severity, comorbid conditions and patient's quality of life warrant prophylactic therapy?
❒ Yes, *Continue to 14*
❒ No, *Continue to 17*

14. Has prophylactic treatment been considered?
❒ Yes, *Continue to 17*
❒ No, *Continue to 15*

15. Please provide a brief rationale as to why prophylactic treatment has not been considered.
_____,
Continue to 17

16. What is the patient's body weight?
_____kg, *No Further Questions*

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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