



**Angioedema Step Therapy**  
**Berinert J0597/ Cinryze J0598/ Ruconest J0596 (C-1 esterase inhibitor, human), Kalbitor (ecallantide) J1290 are non-preferred.**  
**The preferred product is: Firazyr (icatibant acetate) J1744**  
**Prior Authorization Step Therapy Request**  
**Medicare Part B Form**

*Instructions: \* Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

<input type="checkbox"/>	Date Requested _____
	Requestor _____ Clinic name: _____ Phone _____ / Fax _____

**MEMBER INFORMATION**

\*Name: \_\_\_\_\_ \*ID#: \_\_\_\_\_ \*DOB: \_\_\_\_\_

**PRESCRIBER INFORMATION**

\*Name: \_\_\_\_\_  MD  FNP  DO  NP  PA \*Phone: \_\_\_\_\_

\*Address: \_\_\_\_\_ \*Fax: \_\_\_\_\_

**DISPENSING PROVIDER / ADMINISTRATION INFORMATION**

\*Name: \_\_\_\_\_ Phone: \_\_\_\_\_

\*Address: \_\_\_\_\_ Fax: \_\_\_\_\_

**PROCEDURE / PRODUCT INFORMATION**

HCPC Code	Name of Drug <input type="checkbox"/> Self-administered	Dose (Wt: _____ kg Ht: _____ )	Frequency	End Date if known

Chart notes attached. **Other important information:** \_\_\_\_\_

**Diagnosis: ICD10:** \_\_\_\_\_ **Description:** \_\_\_\_\_

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

**CLINICAL INFORMATION**

New Start or Initial Request: (Clinical documentation required for all requests)  
 **Provider has reviewed the attached “Criteria for Approval” and attests the member meets ALL required PA criteria.**  
 If not, please provide **clinical rationale** for formulary exception: \_\_\_\_\_

Continuation Requests: (Clinical documentation required for all requests)  
 **Provider has reviewed the attached “Criteria for Continuation” and attests the member meets ALL required PA Continuation criteria.**  
 Patient had an adequate response or significant improvement while on this medication.  
 If not, please provide clinical rationale for continuing this medication: \_\_\_\_\_

**ACKNOWLEDGEMENT**

**Request By (Signature Required):** \_\_\_\_\_ **Date:** \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

**THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.**

## Prior Authorization Group – Angioedema Drugs PA

### Drug Name(s):

<b>BERINERT</b>	<b>RUCONEST</b>
<b>CINRYZE</b>	<b>C1 ESTERASE INHIBITOR</b>
<b>KALBITOR</b>	<b>ECALLANTIDE</b>
<b>FIRAZYR</b>	<b>ICATIBANT ACETATE</b>

### Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member has tried and failed at least ONE of the formulary alternatives: **Firazyr** OR
  - There is clinical documentation stating formulary alternatives are contraindicated.
3. Drug is being used appropriately per MCG GUIDELINES, CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
  - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
  - Quantity limits and Tiering will be determined by the Plan.

### Exclusion Criteria:

N/A

### Prescriber Restrictions:

N/A

### Coverage Duration:

Approvals will be for 6 months

### FDA Indications:

#### Beriner, Cinryze

- Hereditary angioedema, abdominal, facial, or laryngeal attacks
- Hereditary angioedema; prophylaxis

#### Ruconest, Kalbitor

- Hereditary angioedema, acute attacks

### Off-Label Uses:

#### Beriner, Cinryze

- Acute ST segment elevation myocardial infarction – emergency CABG

### Step Therapy Drug(s) and FDA Indications:

#### Firazyr

- Hereditary angioedema, acute attacks

### Age Restrictions:

**Kalbitor:** 12 years and older

### Other Clinical Considerations:

N/A

**Resources:**

[https://www.micromedexsolutions.com/micromedex2/librarian/CS/25039B/ND\\_PR/evidencexpert/ND\\_P/evidencexpert/DUPLICATIONSHIELDSYN/C/A3C728/ND\\_PG/evidencexpert/ND\\_B/evidencexpert/ND\\_AppProduct/evidencexpert/ND\\_T/evidencexpert/PFActionId/evidencexpert.DoIntegradedSearch?SearchTerm=C1%20Esterase%20Inhibitor%2C%20Human&UserSearchTerm=C1%20Esterase%20Inhibitor%2C%20Human&SearchFilter=filterNone&navitem=searchGlobal#](https://www.micromedexsolutions.com/micromedex2/librarian/CS/25039B/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYN/C/A3C728/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.DoIntegradedSearch?SearchTerm=C1%20Esterase%20Inhibitor%2C%20Human&UserSearchTerm=C1%20Esterase%20Inhibitor%2C%20Human&SearchFilter=filterNone&navitem=searchGlobal#)

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[https://www.micromedexsolutions.com/micromedex2/librarian/CS/D78844/ND\\_PR/evidencexpert/ND\\_P/evidencexpert/DUPLICATIONSHIELDSYN/C/1133E9/ND\\_PG/evidencexpert/ND\\_B/evidencexpert/ND\\_AppProduct/evidencexpert/ND\\_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=931008&contentSetId=100&title=C1+Esterase+Inhibitor+Recombinant&servicesTitle=C1+Esterase+Inhibitor+Recombinant&brandName=Ruconest&UserMdxSearchTerm=Ruconest&=null#](https://www.micromedexsolutions.com/micromedex2/librarian/CS/D78844/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYN/C/1133E9/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=931008&contentSetId=100&title=C1+Esterase+Inhibitor+Recombinant&servicesTitle=C1+Esterase+Inhibitor+Recombinant&brandName=Ruconest&UserMdxSearchTerm=Ruconest&=null#)

CLINICAL / CIMS ONLY