Angioedema Drugs

Takhzyro (lanadelumab-flyo) J0593, Berinert J0597/ Cinryze J0598/ Ruconest / Haegarda J0599 (C-1 esterase inhibitor, human) J0596, Kalbitor (ecallantide) J1290 are non-preferred. The preferred product is (Firazyr (icatibant acetate) J1744

Prior Authorization Step Therapy

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.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	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	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐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)

- ☐ Patient has a diagnosis of hereditary angioedema;
- ☐ Patient is using for prophylaxis against acute attacks of hereditary angioedema for either of the following:
  - ☐ Short-term prophylaxis prior to surgery, dental procedures or intubation; OR
  - ☐ Long-term prophylaxis to minimize the frequency and/or severity of recurrent attacks;
- ☐ Documentation is provided that diagnosis is verified by a C4 level below the lower limit of normal as defined by laboratory test AND any of the following:
  - ☐ C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by lab test; OR
  - ☐ C1-INH functional level below the lower limit of normal as defined by lab test; OR
  - ☐ Presence of a known HAE-causing C1-INH mutation;
- ☐ Patient has a history of moderate or severe attacks such as airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, or painful facial distortion

If not, please provide **clinical rationale** for formulary exception: _____
_____

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ 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):

BERINERT	**RUCONEST**	
CINRYZE	**HAEGARDA**	**C1 ESTERASE INHIBITOR**
KALBITOR	**ECALLANTIDE**	
TAKHZYRO	**LANADELUMAB-FLYO**	
FIRAZYR	**ICATIBANT ACETATE**	

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. 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:

Berinert, Cinryze, Haegarda

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

Takhzyro

- Hereditary angioedema, prophylaxis

Ruconest, Firazyr, Kalbitor

- Hereditary angioedema, acute attacks

Off-Label Uses:

Berinert, Cinryze

- Acute ST segment elevation myocardial infarction – emergency CABG

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/DUPLICATIONSHIELDSYNC/A3C728/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.DoIntegrat

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