



Prior Authorization Protocol

BERINERT® [C1 Esterase Inhibitor (Human)], KALBITOR® (ecallantide), FIRAZYR® (icatibant), RUCONEST® (C1 esterase inhibitor [recombinant])

NATL

Coverage of drugs is first determined by the member's pharmacy or medical benefit. Please consult with or refer to the Evidence of Coverage document.

I. FDA Approved Indications:

BERINERT

- For the treatment of acute abdominal, facial, or laryngeal attacks of hereditary angioedema (HAE) in adult and adolescent patients
The safety and efficacy of Berinert for prophylactic therapy have not been established.

KALBITOR

- For the treatment of acute attacks of hereditary angioedema (HAE) in patients 12 years of age and older.

FIRAZYR

- For treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older

RUCONEST

- For the treatment of acute attacks in adult and adolescent patients with hereditary angioedema (HAE)
Limitation of Use: Effectiveness was not established in HAE patients with laryngeal attacks

II. Health Net Approved Indications and Usage Guidelines:

- For the treatment of acute attacks of HAE
AND
Diagnosis of HAE confirmed by a specialist (hematologist, allergist, immunologist)

III. Coverage is Not Authorized For:

- Non-FDA approved indications, which are not listed in the Health Net Approved Indications and Usage Guidelines section, unless there is sufficient documentation of efficacy and safety in the published literature

IV. General Information:

- Kalbitor should only be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and HAE.
Patients may self-administer Berinert, Firazyr, and Ruconest upon recognition of an HAE attack after training under the guidance of a healthcare professional.

V. Therapeutic Alternatives:

- This section intentionally left blank.

VI. Recommended Dosing Regimen and Authorization Limit:

Table with 3 columns: Drug, Dosing Regimen, Authorization Limit. Row 1: Berinert, Appropriately trained patients may self-administer upon recognition of an HAE attack., HNCA & HNMC: 6 months or to member's

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Drug	Dosing Regimen	Authorization Limit
	20 units per kg body weight by IV injection	renewal period, whichever is longer NATL: Length of benefit
Firazyr	Patients may self-administer upon recognition of an HAE attack. <ul style="list-style-type: none"> • 30 mg injected SC in the abdominal area. • If response is inadequate or symptoms recur, additional injections of 30 mg may be administered at intervals of at least 6 hours. Do not administer more than 3 injections in 24 hours.	HNCA & HNMC: 6 months or to member's renewal period, whichever is longer NATL: Length of benefit
Kalbitor	30 mg administered SC in three 10 mg injections. If an attack persists, an additional 30 mg dose may be administered within a 24 hour period.	HNCA & HNMC: 6 months or to member's renewal period, whichever is longer NATL: Length of benefit
Ruconest	Appropriately trained patients may self-administer upon recognition of an HAE attack. <ul style="list-style-type: none"> • Body weight < 84 kg: 50 units per kg body weight by IV injection • Body weight ≥ 84 kg: 4200 units by IV injection • If an attack persists, an additional (second) dose can be administered at the recommended dose level. • Do not exceed 4200 units per dose • No more than two doses should be administered within a 24 hour period 	HNCA & HNMC: 6 months or to member's renewal period, whichever is longer NATL: Length of benefit

VII. Product Availability:

Berinert: Single-use Vial: 500 units
 Kalbitor: Single-use Vials: 10 mg/mL
 Firazyr: Single-use, prefilled syringe: 30 mg/3 ml
 Ruconest: Single-use Vial: 2100 units

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1. Berinert [Prescribing Information]. Kankakee, IL: CSL Behring LLC; May 2015.
2. Kalbitor [Prescribing Information]. Burlington, MA: Dyax Corp; September 2014.
3. Firazyr [Prescribing Information]. Lexington, MA: Shire Orphan Therapies, Inc., November 2015.
4. Ruconest [Prescribing Information]. Netherlands: Pharming Group N.V. February 2015.
5. Huang SW. Pediatric Angioedema: Differential Diagnoses & Workup. EMedicine website. Available at <http://emedicine.medscape.com/article/885100-workup>. Accessed June 20, 2016.
6. Clinical Pharmacology Web site. Available at: <http://clinicalpharmacology-ip.com/>. Accessed June 20, 2016.
7. Berinert. American Hospital Formulary Service Drug Information. Available at: <http://www.medicinescomplete.com/mc/ahfs/current/>. Accessed June 20, 2016.
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9. Firazyr. American Hospital Formulary Service Drug Information. Available at: <http://www.medicinescomplete.com/mc/ahfs/current/>. Accessed June 20, 2016.
10. DRUGDEX[®] System [Internet database]. Greenwood Village, Colo: Truven Health Analytics. Updated periodically. Accessed June 20, 2016.

The materials provided to you are guidelines used by this health plan to authorize, modify, or determine coverage for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual needs and the benefits covered under your contract.