CareSource

PHARMACY POLICY STATEMENT
Arkansas PASSE

DRUG NAME	Ruconest (C1 esterase inhibitor (recombinant))
BILLING CODE	J0596
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Home/Office
COVERAGE REQUIREMENTS	Prior-Authorization Required (Non-Preferred Product) Alternative preferred products include Berinert and Firazyr QUANTITY LIMIT—8 vials per fill
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Ruconest (C1 esterase inhibitor (recombinant)) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

HEREDITARY ANGIOEDEMA (HAE)

For **initial** authorization:

1. Member must be 13 years of age or older; AND
2. Medication must be prescribed by or in consultation with an allergist or immunologist; AND
3. Member has a diagnosis of HAE type I or type II confirmed by both of the following:
   a) Low C4 level;
   b) Low (<50% of normal) C1 inhibitor antigenic and/or functional level; AND
4. Medication is being prescribed for the treatment of acute HAE attacks; AND
5. Member has documented trial and failure of or contraindication to both Firazyr and Berinert (Chart notes required); AND
6. Medication is not being used in combination with another on-demand therapy (e.g. Berinert, Firazyr, Kalbitor); AND
7. Member does not have a history of allergy to rabbits or rabbit-derived products.
8. **Dosage allowed:** 50 IU per kg IV; not to exceed 4200 IU (2 vials) per dose. May repeat 1 time; no more than 2 doses within 24 hours.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must document improvement such as faster time to symptom relief or resolution of attack.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Ruconest (C1 esterase inhibitor (recombinant)) not medically necessary for the treatment of diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
08/28/2017	New policy for Ruconest created. Criteria for each type of HAE specified. Criteria of documentation of attacks, discontinuation of meds that can cause HAE, and restriction on combinations with other meds for acute attacks added.
01/20/2021	Updated references. Clarified the dosing. Removed statement about causative meds. Removed hematology as specialist. Simplified the diagnostic criteria. Removed log book requirement. Reworded the renewal criteria. Added rabbit allergy contraindication. Extended initial auth duration to 6 mo and renewal to 12 mo. Changed “rabbit-derived” to say “recombinant.” Adjusted quantity limit to allow for repeat doses as indicated. Removed exclusion of laryngeal attacks.

References:

1. Ruconest [package insert]. Warren NJ: Pharming Healthcare, Inc; 2020.
2. Frank MM, Zuraw B, Banerji A, et al. Management of children with hereditary angioedema due to C1 inhibitor deficiency. Pediatrics. 2016 Nov;138(5). pii: e20160575.
3. Riedl MA, Bernstein JA, Li H, et al. Recombinant human C1-esterase inhibitor relieves symptoms of hereditary angioedema attacks: phase 3, randomized, placebo-controlled trial. *Ann Allergy Asthma Immunol*. 2014;112(2):163-169.e1. doi:10.1016/j.anai.2013.12.004
4. Busse PJ, Christiansen SC, Riedl MA, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema [published online ahead of print, 2020 Sep 6]. *J Allergy Clin Immunol Pract*. 2020;S2213-2198(20)30878-3. doi:10.1016/j.jaip.2020.08.046
5. Maurer M, Magerl M, Ansotegui I, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2017 revision and update. *Allergy*. 2018;73(8):1575-1596. doi:10.1111/all.13384

Effective date: 01/01/2022
Revised date: 01/20/2021