

PHARMACY POLICY STATEMENT

Indiana Medicaid

DRUG NAME	Berinert (C1 Esterase Inhibitor (Human))
BILLING CODE	J0597
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Home/Freestanding facility or clinic
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 8 vials per fill (32 vials per month)
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Berinert (C1 Esterase Inhibitor (Human)) is a **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 6 years of age or older, and medication is being used **for the treatment of acute abdominal, facial, or laryngeal HAE attacks** (NOT for treatment of acquired angioedema); AND
2. Medication prescribed by or in consultation with a provider specializing in allergy, immunology, or hematology; AND
3. Member must have a confirmed diagnosis of HAE as **one** of the following:
 - a) Type 1 HAE documented in chart notes with ALL of the following (Note: tests listed below must be repeated for confirmation of diagnosis):
 - i) Low levels (below the limits of the laboratory's normal reference range) of C4, C1-INH antigenic protein and C1-INH functional level; AND
 - ii) Positive family history of angioedema OR earlier age of onset (before age 30) with normal C1q antigenic protein level;
 - b) Type 2 HAE documented in chart notes with ALL of the following (Note: tests listed below must be repeated for confirmation of diagnosis):
 - i) Normal or elevated level of C1-INH antigenic protein (as defined by performing lab); AND
 - ii) Low level (below the limits of the laboratory's normal reference range) C4 and C1-INH functional; AND
4. Medication is **not** being used in combination with Kalbitor, Firazyr, or Ruconest; AND
5. Medications known to cause angioedema (i.e., ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate.
6. **Dosage allowed:** Dose of 20 International Units (IU) per kg body weight by intravenous injection.

Note: Personal documentation (log book, journal, etc.) of medication use will be necessary for reauthorization. Prescribers should be aware and make their patients aware of this requirement for reauthorization.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease; AND
3. Log of medication use supported by medical chart or by claims data has been provided.

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

CareSource considers Berinert (C1 Esterase Inhibitor (Human)) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- HAE prophylactic therapy
- Acquired angioedema (AAE)

DATE	ACTION/DESCRIPTION
08/25/2017	New policy for Berinert 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 were added.

References:

1. Bowen T, Cicardi M, Farkas H, et al. 2010 International consensus algorithm for the diagnosis, therapy, and management of hereditary angioedema. *Allergy Asthma Clin Immunol.* 2010;6(1):24.
2. Craig, T., Pürsün, E. A., Bork, K., Bowen, et al. (2012). WAO Guideline for the Management of Hereditary Angioedema. *The World Allergy Organization Journal*, 5(12), 182–199. <http://doi.org/10.1097/WOX.0b013e318279affa>.
3. Berinert [package insert]. Kankakee, IL: CSL Behring LLC; September, 2016.
4. Berinert. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: <http://www.micromedexsolutions.com>. Accessed August 8, 2017.

Effective date: 01/01/2018

Revised date: 08/25/2017