CareSource

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	**Berinert (C1 esterase inhibitor (human))**
BILLING CODE	**J0597**
BENEFIT TYPE	**Medical**
SITE OF SERVICE ALLOWED	**Home/Office**
COVERAGE REQUIREMENTS	**Prior Authorization Required (Preferred Product)** **QUANTITY LIMIT— 8 vials per fill**
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. **Medication must be prescribed by or in consultation with an allergist or immunologist; AND**
2. **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**
3. **Medication is being prescribed for the treatment of acute HAE attacks; AND**
4. **Medication is not being used in combination with another on-demand therapy (e.g. Kalbitor, Firazyr, Ruconest).**
5. **Dosage allowed: 20 International Units (IU) per kg body weight by IV injection.**

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 Berinert (C1 esterase inhibitor (human)) not medically necessary for the treatment of diseases that are not listed in this document.

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.
01/15/2021	Updated references. Removed age limit. Removed hematology as specialist. Simplified the diagnostic criteria. Removed specific body locations from indication, per clinical guidelines. Removed log book requirement. Reworded the renewal criteria. Extended

	initial approval duration to 6 months and renewal to 12 months. Removed statement about causative meds. Deleted monthly quantity limit.

References:

1. Berinert [package insert]. Kankakee, IL: CSL Behring LLC; 2020.
2. 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
3. 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
4. Craig TJ, Levy RJ, Wasserman RL, et al. Efficacy of human C1 esterase inhibitor concentrate compared with placebo in acute hereditary angioedema attacks. J Allergy Clin Immunol. 2009;124(4):801-808. doi:10.1016/j.jaci.2009.07.017

Effective date: 07/01/2021
Revised date: 01/15/2021