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5.85.02

Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Hematological Agents	**Original Policy Date:**	June 9, 2011
Subject:	Berinert	**Page:**	1 of 4

Last Review Date: March 12, 2021

Berinert

Description

Berinert (C1 esterase inhibitor [human])

Background
Berinert is a human plasma derived C1-esterase inhibitor for the treatment of acute attacks in adult and pediatric patients with hereditary angioedema (HAE). Hereditary angioedema, which is caused by having insufficient amounts of a plasma protein called C1-esterase inhibitor. People with HAE can develop rapid swelling of the hands, feet, limbs, face, intestinal tract, or airway. These acute attacks of swelling can occur spontaneously, or can be triggered by stress, surgery or infection. Swelling of the airway is potentially fatal without immediate treatment. Berinert is intended to restore the level of functional C1-esterase inhibitor in a patient's plasma, thereby treating the acute attack of swelling (1).

Regulatory Status
FDA-approved indication: Berinert is a plasma-derived C1 Esterase Inhibitor (Human) indicated for the treatment of acute abdominal, facial, or laryngeal attacks of hereditary angioedema (HAE) in adult and pediatric patients (1).

Hypersensitivity reactions may occur. Epinephrine should be immediately available to treat any acute severe hypersensitivity reactions following discontinuation of administration (1).

Thrombotic events have been reported at the recommended dose of C1 Esterase Inhibitor (Human) products, including Berinert, following treatment of HAE. Monitor closely patients with known risk factors for thrombotic events (1).

Berinert is made from human plasma and may contain infectious agents, e.g., viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent (1).

Following self-administration of Berinert for laryngeal attacks, advise patients to immediately seek medical attention (1).

The safety and efficacy of Berinert for prophylactic therapy have not been established (1).

The safety and efficacy of Berinert in pediatric patients less than 5 years of age have not been established (1).

Related policies
Cinryze, Firazyr, Haegarda, Kalbitor, Orladeyo, Ruconest, Takhzyro

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Berinert may be considered **medically necessary** in patients 5 years of age or older for the treatment of acute attacks of hereditary angioedema (HAE) and if the conditions indicated below are met.

Berinert may be considered **investigational** in patients under 5 years of age and for all other indications.

Prior-Approval Requirements

Age 5 years of age and older

Diagnosis

Patient must have the following:

1. Acute attacks of Hereditary Angioedema (HAE)

AND NONE of the following:
   a. Prophylactic therapy
   b. Dual therapy with another agent for treating acute attacks of HAE

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Berinert is a C1 esterase inhibitor [plasma derived] indicated for the treatment of acute attacks in adult and pediatric patients with hereditary angioedema (HAE). HAE symptoms include episodes of edema (swelling) in various body parts including the hands, feet, face, and airway. HAE is caused by mutations to C1-esterase-inhibitor (C1-INH). Serious arterial and venous thromboembolic (TE) events have been reported at the recommended dose of plasma derived C1 esterase inhibitor products in patients with risk factors (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Berinert while maintaining optimal therapeutic outcomes.

References

1. Berinert [package insert]. Kankakee, IL: CSL Behring LLC.; March 2020.

Policy History

Date	Action
June 2011	New Policy
January 2012	FDA approved new indication of treatment of acute laryngeal attacks of hereditary angioedema (HAE) in adult and adolescent patients
September 2012	Annual Review-editorial and reference update
March 2013	Annual editorial review

March 2014	Annual review
December 2014	Annual editorial review and reference update Addition of the no dual therapy with another agent for treating acute attacks of HAE and removal of areas
December 2015	Annual review and reference update
August 2016	Addition of pediatric patients 5 years of age and older Policy number change from 5.10.02 to 5.85.02
December 2016	Annual editorial review and reference update
September 2017	Annual editorial review and reference update
December 2017	Annual review
September 2018	Annual review and reference update
November 2018	Annual review
September 2019	Annual review and reference update
September 2020	Annual review
March 2021	Annual editorial review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.