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 adolescent 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 (1-2).

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 adolescent patients (2).

Hypersensitivity reactions may occur. Epinephrine should be immediately available to treat any acute severe hypersensitivity reactions following discontinuation of administration (2).

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 (2).
Berinert is made from human plasma and may contain infectious agents, e.g., viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent (2).

Following self-administration of Berinert for laryngeal attacks, advise patients to immediately seek medical attention (2).

The safety and efficacy of Berinert for prophylactic therapy have not been established (2). The safety and efficacy of Berinert in children (age 0 through 12) have not been established (2).

Related policies
Cinryze, Kalbitor, Firazyr, Ruconest

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 12 years of age or older for the treatment of acute attacks of hereditary angioedema (HAE); not for prophylactic therapy, and no dual therapy with another agent for treating acute attacks of HAE.

Berinert may be considered investigational in patients under age 12 with HAE and in patients without a diagnosis of HAE.

Prior-Approval Requirements

Age
12 years of age and older

Diagnosis

Patient must have the following:

1. Acute attacks of Hereditary Angioedema (HAE)

AND NONE of the following:

1. Prophylactic therapy
2. 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

Duration 12 months

Rationale

Summary

Berinert is a C1 esterase inhibitor [plasma derived] indicated for the treatment of acute attacks in adult and adolescent 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. The safety and efficacy of Bernert in children less than 12 years of age has not been established (2).

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

References
Section: Prescription Drugs  Effective Date: January 1, 2016
Subsection: Hematological Agents  Original Policy Date: June 9, 2011
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<tr>
<td>June 2011</td>
<td>New Policy</td>
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<tr>
<td>January 2012</td>
<td>FDA approved new indication of treatment of acute laryngeal attacks of hereditary angioedema (HAE) in adult and adolescent patients</td>
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<td>September 2012</td>
<td>Annual Review-editorial and reference update</td>
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<td>March 2013</td>
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<td>December 2014</td>
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<td>Addition of the no dual therapy with another agent for treating acute attacks of HAE and removal of areas</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 3, 2015 and is effective January 1, 2016.

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