Ruconest

Description

Ruconest (C1 esterase inhibitor [recombinant])

Background
Ruconest is a human recombinant C1-esterase inhibitor for the treatment of acute attacks in adult and adolescent patients with hereditary angioedema (HAE). Hereditary angioedema is caused by having insufficient amounts of a plasma protein called C1-esterase inhibitor. People with HAE can develop rapid swelling of various parts of the body. Swelling of the airway is potentially fatal without immediate treatment. Ruconest 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: Ruconest is a C1 esterase inhibitor [recombinant] indicated for the treatment of acute attacks in adult and adolescent patients with hereditary angioedema (HAE) (1).

Limitations of Use:
Effectiveness was not established in HAE patients with laryngeal attacks (1).

Patients, with known risk factors, should be monitored for thromboembolic (TE) events during and after Ruconest administration. 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. Risk factors may include the presence of an indwelling venous
Ruconest may be considered **medically necessary** in patients 13 years of age or older for the treatment of acute attacks of hereditary angioedema (HAE) in locations other than laryngeal attacks; and no dual therapy with another agent for treating acute attacks of HAE.

Ruconest may be considered **investigational** in patients less than 13 years of age and for all other indications.

**Prior-Approval Requirements**

**Age**

13 years of age and older

**Diagnosis**

Patient must have the following:

1. Acute attacks of Hereditary Angioedema (HAE)

**AND NONE** of the following:

1. Laryngeal attacks
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
Ruconest is a C1 esterase inhibitor [recombinant] indicated for the treatment of acute attacks in adult and adolescent patients with hereditary angioedema (HAE). Effectiveness was not established in HAE patients with laryngeal attacks. 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 Ruconest in children less than 13 years of age have not been established (1).

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

References

Policy History

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<tr>
<td>August 2014</td>
<td>Addition to PA</td>
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<tr>
<td>December 2014</td>
<td>Annual editorial review and reference update</td>
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<tr>
<td>December 2015</td>
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<td>December 2016</td>
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Keywords
This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 2, 2016 and is effective on January 1, 2017.

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