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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Hematological Agents	**Original Policy Date:**	August 22, 2014
Subject:	Ruconest	**Page:**	1 of 4

Last Review Date: March 12, 2021

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

catheter/access device, prior history of thrombosis, underlying atherosclerosis, use of oral contraceptives or certain androgens, morbid obesity, and immobility (1).

The safety and efficacy of Ruconest in pediatric patients less than 13 years of age have not been established (1).

Related policies
Berinert, Cinryze, Firazyr, Haegarda, Kalbitor, Orladeyo, 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.

Ruconest may be considered **medically necessary** in patients 13 years of age or older for the treatment of acute attacks of hereditary angioedema (HAE) and if the conditions indicated below are met.

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
Same as above

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 pediatric patients 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
1. Ruconest [package insert]. Bridgewater, NJ: Pharming Healthcare Inc.; April 2020.

Policy History

Date	Action
August 2014	Addition to PA
December 2014	Annual editorial review and reference update
December 2015	Annual editorial review
December 2016	Annual editorial review and reference update Policy code changed from 5.10.17 to 5.85.17
September 2017	Annual review and reference update
December 2017	Annual review
September 2018	Annual review and reference update
November 2018	Annual review
September 2019	Annual review

September 2020	Annual review and reference update
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.