BlueCross BlueShield Federal Employee Program

RUCONEST
(C1 esterase inhibitor [recombinant])

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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).

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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.