Ruconest® (recombinant C1 esterase inhibitor)

When requesting Ruconest (recombinant C1 esterase inhibitor), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines for the covered indication.

FDA-approved Indication

Ruconest is indicated for the treatment of acute attacks of Hereditary Angioedema (HAE).

Coverage Guidelines

Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] – Treatment of Acute Attacks

The patient must meet **all** of the following criteria for initial authorization:

- The patient has HAE type I or type II as confirmed by the following diagnostic criteria:
    - Patient has low levels of functional C1-INH protein (less than 50% of normal) at baseline, as defined by the laboratory reference values; AND
    - Patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values; AND
- The medication is prescribed by or in consultation with an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders.

Approval duration: 12 months

The patient must meet **all** of the following criteria for reauthorization:

- The patient has treated previous acute HAE type I or type II attacks with Ruconest;
- According to the prescribing physician, the patient has had a favorable clinical response (e.g., decrease in the duration of HAE attacks, quick onset of symptom relief, complete resolution of symptoms, decrease in HAE acute attack frequency or severity) with Ruconest treatment; AND
- The medication is prescribed by on in consultation with an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders.

Approval duration: 12 months

Dosing Recommendation

Approve up to a maximum dose of 50 international units/kg (maximum 4,200 international units) intravenously, no more frequently than twice daily.

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References

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