PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Hereditary Angioedema – C1 Esterase Inhibitors (Intravenous) Preferred Specialty Management Policy
- Berinert® (C1 esterase inhibitor [human] intravenous infusion – CSL Behring)
- Ruconest® (recombinant C1 esterase inhibitor intravenous infusion – Pharming)

REVIEW DATE: 12/21/2022

OVERVIEW

Berinert and Ruconest are C1 esterase inhibitors indicated for **hereditary angioedema**. Berinert, a plasma-derived product, is indicated for the treatment of acute abdominal, facial, or laryngeal attacks in adult and pediatric patients.[1] Ruconest, a recombinant product, is indicated for the treatment of acute attacks in adult and adolescent patients.[2] The prescribing information notes a Limitation of Use that effectiveness of Ruconest has not been established in laryngeal attacks. Ruconest is purified from the milk of transgenic rabbits and is contraindicated in patients with allergy to rabbits or rabbit-derived products.

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of the Preferred Product. For both medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *Prior Authorization Policy* criteria. The program also directs the patient to try one Preferred Product prior to the approval of the Non-Preferred Product. Requests for the Non-Preferred Product will also be reviewed using the exception criteria (below). If the patient meets the standard *Hereditary Angioedema – C1 Esterase Inhibitors (Intravenous) Prior Authorization Policy* criteria for Berinert but has not tried Ruconest, a review will be offered for the Preferred Product using the respective standard *Hereditary Angioedema – C1 Esterase Inhibitors (Intravenous) Prior Authorization Policy* criteria for Ruconest. All approvals are provided for 1 year in duration. Note: Cinryze® (C1 esterase inhibitor [human] intravenous infusion) is not addressed in this policy.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information.

Automation: None.

Preferred Product: Ruconest
Non-Preferred Product: Berinert

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Berinert	**1. <u>Hereditary Angioedema Due to C1 Inhibitor Deficiency (Type I or II), Treatment of Acute Attacks</u>.** **A)** Approve for 1 year if the patient meets the following criteria (i <u>and</u> ii): **i.** Patient meets the standard *Hereditary Angioedema – C1 Esterase Inhibitors (Intravenous) Prior Authorization Policy* criteria for Berinert; AND **ii.** Patient meets one of the following criteria (a, b, c, <u>or</u> d): **a)** Patient has tried the Preferred Product, Ruconest **[documentation required]**; OR **b)** Patient has had a of at least one laryngeal attack that had been treated with Berinert, as per the prescriber; OR **c)** Patient has an allergy to rabbits or rabbit-derived products; OR **d)** Patient is less than 13 years of age. **B)** For a patient who meets the standard *Hereditary Angioedema – C1 Esterase Inhibitors (Intravenous) PA Policy* criteria for Berinert but has not tried the Preferred Product (Ruconest), offer to review for Ruconest using the standard *Hereditary Angioedema – C1 Esterase Inhibitors (Intravenous) Prior Authorization Policy* criteria for Ruconest. **2. <u>Other Conditions</u>.** Approve for 1 year if the patient meets the standard *Hereditary Angioedema – C1 Esterase Inhibitors (Intravenous) Prior Authorization Policy* criteria for Berinert.

REFERENCES

1. Berinert® intravenous infusion [prescribing information]. Kankakee, IL: CSL Behring; September 2021.
2. Ruconest® intravenous infusion [prescribing information]. Warren, NJ: Pharming; April 2020.