



Prior Authorization Approval Criteria

Cinryze (C1 Inhibitor Human)

Generic name:	C1 Inhibitor Human
Brand name:	Cinryze
Medication class:	Blood product derivative, immune modulator
FDA-approved uses:	Prevention therapy against angioedema attacks in patients with hereditary angioedema or C1 inhibitor deficiency from birth
Available dosage forms:	Lyophilized solution for injection
Usual dose:	1000 units intravenously at an infusion rate of 1mL/min over 10 minutes every 3 to 4 days
Approximate monthly cost:	(based on AWP 12/1/08) \$27,000 to \$36,000 per month
Duration of therapy:	Indeterminate

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

- Diagnosed and prescribed by a specialist
- Documentation of clinical diagnosis of hereditary angioedema or C1 inhibitor deficiency from birth and having angioedema attacks
- 9 years or older
- Patient is not hypersensitive to Cinryze or any of its components
- Documentation of a monitoring plan
- Request will be reviewed by a Medical Director

Criteria for continuation of therapy:

- No symptoms of hypersensitivity such as wheezing, hypotension, chest tightness, hives

Caution:

- Hypersensitivity reaction
- Patients with risk factors for blood clots
- Possible transmission of infectious agents or viruses

Monitoring:

- Decrease in number, severeness and length of angioedema attacks
- Symptoms of hypersensitivity
- Signs of blood clots such as swelling, pain in limbs or abdomen, shortness of breath, abnormal consciousness or speech, chest pain, loss of feeling

Contraindication: Hypersensitivity to Cinryze or any of its components

Not approved if: Above-stated criteria are not met

Special considerations:

- Safety and efficacy not established in pregnant, neonates, infants or children
- Restricted distribution. Currently only available through CINRYZESolutions™ Support Program (Patient Intake Hub), Caremark Specialty Pharmacy, and CuraScript Specialty Distribution

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 12/10/2008
Revised: 4/30/2009