



STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES



Office of Pharmacy Service
Prior Authorization Criteria

HEREDITARY ANGIOEDEMA AGENTS
Cinryze® & Haegarda® (human C1-inhibitor)
Takhzyro® (lanadelumab)
Effective 05/24/2019

[Prior Authorization Request Form](#)

CINRYZE and HAEGARDA are plasma-derived concentrates of C1 esterase inhibitor (human) (C1-INH) indicated for routine prophylaxis to prevent Hereditary Angioedema Attacks (HAE).

TAKHZYRO is a plasma kallikrein inhibitor (monoclonal antibody) indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE).

CRITERIA FOR APPROVAL

- 1) The diagnosis of hereditary angioedema (HAE) must be clinically established by, or in consultation with, an allergist or immunologist; **AND**
- 2) The patient must meet the individual age restrictions outlined in the FDA-approved label for the requested agent; **AND**
- 3) Diagnosis of HAE must be documented and based on evidence of low C4 level AND one of the following:
 - a. A low C1 inhibitor (C1-INH) antigenic level; **OR**
 - b. A normal C1-INH antigenic level and a low C1-INH functional level;

AND

- 4) The member has a history of more than one moderate to severe attack per month (i.e. swelling of the face, throat, or abdomen); **AND**
- 5) Baseline frequency of HAE attacks must be documented; **AND**
- 6) The member is not concurrently taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy or any other medication known to cause potentially cause angioedema; **AND**
- 7) The recipient has had an insufficient response or contraindication to therapy with a 17 α – alkylated androgen (e.g. danazol, stanozolol, oxandrolone, methyltestosterone). **This requirement is waived for growing children and for pregnant or lactating females.**

Initial approvals are for 6 months.

CONTINUATION OF THERAPY CRITERIA

Medical records documenting a decrease of at least 50% in the frequency of attacks and significant improvement in severity and duration of attacks must be provided.



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REFERENCES

- 1) Cinryze package insert 06/2018
- 2) Haegarda package insert 10/2017
- 3) Takhzyro package insert 11/2018
- 4) Lexi-Comp Clinical Application 11/12/2017
- 5) UpToDate Articles accessed 05/03/19: Hereditary Angioedema and Pathogenesis;
Hereditary Angioedema- General Care and Long-term Prophylaxis
- 6) US Hereditary Angioedema Association Medical Advisory Board 2013 Recommendations for
the Management of Hereditary Angioedema Due to C1 Inhibitor Deficiency; J ALLERGY
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