Cinryze (C1 esterase inhibitor [human])

Line(s) of Business: HMO; PPO; QUEST Integration; Medicare Advantage

Original Effective Date: 10/01/2015
Current Effective Date: 01/01/2018

POLICY

A. INDICATIONS
The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
- Routine prophylaxis against angioedema attacks in adolescent and adult patients with hereditary angioedema (HAE)

B. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review:
- Laboratory report with C4 level, C1 inhibitor antigenic protein level and/or C1 inhibitor functional activity
- For the diagnosis of HAE with normal C1 inhibitor, F12 gene mutation testing results (if applicable)

C. CRITERIA FOR APPROVAL
Hereditary Angioedema
Authorization of 12 months may be granted to members who meet ALL of the following criteria:
1. Member is at least 9 years of age
2. Cinryze is being requested for the prophylaxis of HAE attacks
3. Diagnostic laboratory testing for HAE has been performed including C4 level, C1 inhibitor antigenic protein level and/or C1 inhibitor functional activity
4. For members with HAE with C1 inhibitor deficiency (HAE type I or type II):
   a. Low C4 level, and
   b. Low C1 inhibitor antigenic protein level and/or low C1 inhibitor functional activity (below the lower limit of normal as defined by the laboratory performing the test)
5. For members with HAE with normal C1 inhibitor (HAE type III):
   a. Normal C4 level, normal C1 inhibitor antigenic protein level and normal C1 inhibitor functional activity
   b. Member meets EITHER of the following criteria:
      i. Member tested positive for the F12 gene mutation
      ii. Member has a family history of angioedema
   c. Other causes of angioedema have been ruled out (eg, drug-induced)
D. CONTINUATION OF THERAPY
   1. No previous authorization/precertification:
      All members (including members currently receiving treatment without prior authorization)
      must meet criteria for initial approval in section C.
   2. Reauthorization:
      Authorization of 12 months may be granted to members requesting authorization for
      continuation of therapy if Cinryze was previously authorized by HMSA/CVS and member
      demonstrated a clinical response to therapy.

E. DOSAGE AND ADMINISTRATION
   Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted
   compendia, and/or evidence-based practice guidelines.

F. ADMINISTRATIVE GUIDELINES
   Precertification is required. Please refer to the HMSA medical policy web site for the fax form.

G. IMPORTANT REMINDER
   The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not
   intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended
   to discourage or prohibit providing other medical advice or treatment deemed appropriate by the
   treating physician.

   Benefit determinations are subject to applicable member contract language. To the extent there are
   any conflicts between these guidelines and the contract language, the contract language will
   control.

   This Medical Policy has been developed through consideration of the medical necessity criteria
   under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4),
   generally accepted standards of medical practice and review of medical literature and government
   approval status. HMSA has determined that services not covered under this Medical Policy will not
   be medically necessary under Hawaii law in most cases. If a treating physician disagrees with
   HMSA’s determination as to medical necessity in a given case, the physician may request that
   CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light
   of any supporting documentation.

H. REFERENCES
   2. Bowen T, Cicardi M, Farkas H, et al. 2010 International consensus algorithm for the diagnosis,
      Evidence-based recommendations for the therapeutic management of angioedema owing to


Document History

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