CareFirst Family of health care plans

CVS caremark™

ENHANCED SPECIALTY GUIDELINE MANAGEMENT

HAEGARDA (C1 Esterase Inhibitor Subcutaneous [Human])

POLICY

I. 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 Indication
Routine prophylaxis to prevent Hereditary Angioedema (HAE) attacks in adolescent and adult patients.

All other indications are considered experimental/investigational and are not a covered benefit.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review: C4 levels and C1 inhibitor functional and antigenic protein levels.

III. CRITERIA FOR INITIAL APPROVAL

Authorization of 12 months may be granted for prevention of hereditary angioedema attacks when both of the following criteria are met:

1. Member has C1 inhibitor deficiency as confirmed by laboratory testing OR member has normal C1 inhibitor as confirmed by laboratory testing and meets one of the following criteria:
   a. Member has an F12 gene mutation as confirmed by genetic testing or
   b. Member has a family history of angioedema and the angioedema was refractory to a trial of antihistamine (e.g., cetirizine) for at least one month.
2. Member has experienced an inadequate response or intolerance to danazol or has a clinical reason to avoid danazol such as one of the following:
   a. Undiagnosed abnormal genital bleeding
   b. Markedly impaired hepatic, renal, or cardiac function
   c. Pregnancy (member is currently pregnant or may become pregnant)
   d. Breast feeding
   e. Porphyria
   f. Androgen-dependent tumor
   g. Active thrombosis or history of thromboembolic disease
   h. Prepubertal child

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continuation of therapy when all of the following criteria are met:

1. Member meets the criteria for initial approval.
2. Member has experienced reduction in frequency, severity and duration of attacks since starting treatment.

V. REFERENCES

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13. Farkas H, Martinez-Saguer I, Bork K, et al. International consensus on the diagnosis and management of pediatric patients with hereditary angioedema with C1 inhibitor deficiency. *Allergy*. 2017;72(2):300-313.