CareSource

PHARMACY POLICY STATEMENT
Ohio Medicaid

DRUG NAME	Haegarda (C1 esterase inhibitor (human))
BILLING CODE	J0599
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Home/Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product)
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Haegarda (C1 esterase inhibitor (human)) is a **preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

HEREDITARY ANGIOEDEMA (HAE)

For **initial** authorization:

1. Member must be 6 years of age or older; AND
2. Medication must be prescribed by or in consultation with an allergist or immunologist; AND
3. Member has a diagnosis of HAE type I or type II confirmed by both of the following:
   a) Low C4 level;
   b) Low (<50% of normal) C1 inhibitor antigenic and/or functional level; AND
4. Chart notes must document the member's baseline frequency of HAE attacks; AND
5. Member is inadequately controlled with on-demand treatment alone; AND
6. Haegarda is being prescribed for ongoing prophylaxis and will not be used to treat acute attacks.
7. **Dosage allowed:** 60 units/kg subQ twice weekly (every 3 or 4 days).

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must be provided that show a reduced frequency or number of acute attacks since starting treatment.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Haegarda (C1 esterase inhibitor (human)) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Acquired angioedema (AAE)
- Treatment of acute HAE attacks

DATE	ACTION/DESCRIPTION
08/25/2017	New policy for Haegarda created.

01/14/2021	Updated and revised all content; consistent with other HAE prophylactics. Added specific J code. Changed age limit to 6 per recent label change. Updated references. Greatly simplified the diagnostic confirmation criteria. Removed minimum required number of attacks, per guidelines; will just ask for baseline measure. Removed the statement about causative medications. Added that they must try on-demand treatment first. Rewrote the renewal criteria and removed log book requirement. Extended initial auth duration to 6 mo and renewal to 12 mo. Inserted the word “esterase” in front of “inhibitor” in the drug name.

References:

1. ClinicalTrials.gov web site. Bethesda, MD. U.S. National Institutes of Health. Identifier NCT02584959, Study to Evaluate the Clinical Efficacy and Safety of Subcutaneously Administered C1 Esterase Inhibitor for the Prevention of Angioedema Attacks in Adolescents and Adults With Hereditary Angioedema; October 20, 2015. Available at: https://clinicaltrials.gov/ct2/show/NCT02584959.
2. Haegarda (C1 Esterase Inhibitor [Human]) [prescribing information]. Kankakee, IL: CSL Behring LLC; 2020.
3. Longhurst H, Cicardi M, Craig T, et al. Prevention of Hereditary Angioedema Attacks with a Subcutaneous C1 Inhibitor. N Engl J Med. 2017;376(12):1131-1140.
4. Lumry W. Management and Prevention of Hereditary Angioedema Attacks. Am J Manag Care. 2013;19:S111-S118.
5. Lumry WR, Martinez-Saguer I, Yang WH, et al. Fixed-Dose Subcutaneous C1-Inhibitor Liquid for Prophylactic Treatment of C1-INH-HAE: SAHARA Randomized Study. *J Allergy Clin Immunol Pract*. 2019;7(5):1610-1618.e4. doi:10.1016/j.jaip.2019.01.021
6. Busse PJ, Christiansen SC, Riedl MA, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema [published online ahead of print, 2020 Sep 6]. *J Allergy Clin Immunol Pract*. 2020;S2213-2198(20)30878-3. doi:10.1016/j.jaip.2020.08.046
7. Maurer M, Magerl M, Ansotegui I, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2017 revision and update. *Allergy*. 2018;73(8):1575-1596. doi:10.1111/all.13384

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