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
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:


Effective date: 07/01/2021
Revised date: 01/14/2021