

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

\*FHK- Florida Healthy Kids

## Haegarda (C1 esterase inhibitor [Human])

DRUG.00058

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Haegarda (C1 esterase inhibitor [Human]) subcutaneous injection	May be subject to quantity limit

### APPROVAL CRITERIA

Requests for Haegarda (C1 esterase inhibitor [Human]) may be approved for *prophylaxis* against acute attacks of hereditary angioedema in individuals who meet the following criteria:

- I. Individual is 12 years of age or older; **AND**
- II. Individual has a diagnosis of Hereditary Angioedema (HAE) confirmed by a C4 level below the lower limit of normal as defined by the laboratory performing the test **AND** ANY of the following (A, B, or C);
  - A. C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the test; **OR**
  - B. C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test; **OR**
  - C. The presence of a known HAE-causing C1-INH mutation; **AND**
- III. There is a history of moderate or severe attacks (for example, airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, painful facial distortion); **AND**
- IV. Haegarda is being used for prophylaxis for EITHER of the following (a or b) indications:
  - A. Short term prophylaxis prior to surgery, dental procedures or intubation; **OR**
  - B. Long-term prophylaxis and the individual has failed, is intolerant to, or has a contraindication (for example, under the age of 12, or pregnant, or breastfeeding) to 17 alpha-alkylated androgens (for example, danazol) or antifibrinolytic agents (for example, aminocaproic acid).

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State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

**Key References:**

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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11. Firazyr [Prescribing Information], Lexington, MA. Shire Orphan Therapies, Inc. August 30, 2013. Available at: [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2013/022150s004lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022150s004lbl.pdf). Accessed on July 12, 2017.
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