

# HAEGARDA (C1 esterase inhibitor [human])

## RATIONALE FOR INCLUSION IN PA PROGRAM

## **Background**

Haegarda is a C1-esterase inhibitor used for the routine prophylaxis against angioedema attacks in patients with hereditary angioedema (HAE). HAE is caused by having insufficient amounts of a plasma protein called C1-esterase inhibitor. People with HAE can develop rapid swelling of the hands, feet, limbs, face, intestinal tract, or airway. These acute attacks of swelling can occur spontaneously, or can be triggered by stress, surgery, or infection. Swelling of the airway is potentially fatal without immediate treatment. Haegarda is intended to restore the level of functional C1-esterase inhibitor in a patient's plasma, thereby preventing the acute attack of swelling (1-4).

## **Regulatory Status**

FDA-approved indication: Haegarda is a plasma-derived concentrate of C1 Esterase Inhibitor (Human) (C1-INH) indicated for routine prophylaxis to prevent Hereditary Angioedema (HAE) attacks in patients 6 years of age and older (2).

Hypersensitivity reactions may occur. Epinephrine should be immediately available to treat any acute severe hypersensitivity reactions following discontinuation of administration (2).

Thrombotic events may occur with Haegarda treatment. Monitor closely patients with known risk factors for thrombotic events (2).

#### Summary

Haegarda is a C1-esterase inhibitor indicated for routine prophylaxis against angioedema attacks in patients 6 years of age and older with Hereditary Angioedema (HAE). HAE symptoms include episodes of edema (swelling) in various body parts including the hands, feet, face, and airway. HAE is caused by mutations to C1-esterase-inhibitor (C1-INH). The safety and efficacy of Haegarda in children less than 6 years of age has not been established. Persons who experience frequent and/or severe episodes may be candidates for prophylactic treatment (1-4).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Haegarda while maintaining optimal therapeutic outcomes.



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#### References

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