Vault PromoMats

Electronic Certificate

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Document Name: REAPPROVAL USA-HGD-0418 HAE C1NH Letter of Medical Necessity

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Certification Statement
We certify that the final electronic form of this material is in accordance with each stated region's regulatory requirements, and is a fair and truthful presentation of the facts about the product.

Role	Signature
Role: Approver Workflow: Review & Approve Outcome: Approved	Name: Jonna Coachman (u0056853@cslbehring.com) Date: 11-Jun-2025 18:29:59 GMT+0000 Statement: Review this document, and provide your approval outcome when completing the task.

SAMPLE LETTER OF MEDICAL NECESSITY

[Date]

[Contact name of medical director or payer representative, title]

[Name of health insurance company]

Re: Letter of Medical Necessity for HAEGARDA®, C1 Esterase Inhibitor Subcutaneous (Human), J0599 Injection, C1 Esterase Inhibitor (human)

Patient: [Patient Name] Group/Policy Number: [Number]

Diagnosis: [Code and Description] Denial letter reference number: [Number]

Date of Service: [Date]

I have recently received a [Denial for Coverage] for HAEGARDA because [Reason for Denial-ie, lack of original lab tests]. This letter serves as a request for reconsideration of HAEGARDA coverage for [Patient Name].

[Patient Name] has been under my treatment for the diagnosis of [Diagnosis Information] since [Date]. The patient has been treated with HAEGARDA since [Date] and has been well controlled. We have been unable to locate the original, pre-treatment lab work demonstrating levels of C1-INH protein, C4 concentration, and C1-INH function.

The 2020 US HAEA Guidelines state, "Once C1INH deficiency has been established by laboratory testing, further repeated testing is neither necessary nor useful."[1]

According to the 2021 WAO/EAACI Guidelines, "The recommendation to repeat testing for C1-INH function, C1-INH protein, and C4 refers only to the initial diagnosis of HAE. There is no indication for repeated testing once the diagnosis has been established. Of note, confirmation of HAE by repeat testing, in patients who tested positive, must not delay effective treatment."[2]

- Per the 2021 WAO/EAACI Guidelines, all patients suspected to have HAE should be assessed for blood levels of C1-INH function, C1-INH protein, and C4 to establish a diagnosis. [2]
- The administration of HAEGARDA increases plasma levels of C1-INH in a dose-dependent manner, and subsequently increases plasma concentrations of C4.[3] The C4 plasma concentrations after SC administration of 60 IU/kg HAEGARDA were in the normal range (16 to 38 mg/dL).
- During the HAEGARDA COMPACT Phase 3 OLE trial, the mean steady-state C1-INH functional activity increased to 66.6% with SC use of HAEGARDA 60 IU/kg.

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.

Thank you in advance for your immediate attention to the request.

Sincerely,

[Physician Name, Degree Initials and Practice name]

Enclosures:

[Original Claim Form]

[Denial/Explanation of Benefits]

REFERENCES:

1. Busse PJ, Christiansen SC, Riedl MA, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. J Allergy Clin Immunol Pract. 2021;9(1):132-150.
2. Maurer M, Magerl M, Betschel S, et al. The international WAO/EAACI guideline for the management of hereditary angioedema – the 2021 revision and update. World Allergy Organ J. 2022;15(100627):1-39.
3. HAEGARDA. Prescribing information. CSL Behring; 2022.

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