**Appeal Letter**

**[Insert physician letterhead]**

[Name of Medical Director listed on Denial]

[Insurance Company]

[Address]

[City, State, Zip]

RE: [Patient First Name, Middle Initial, Last Name]

DOB: [ ]

Policy #: [ ]

Claim #: [ ]

Dear [Medical Director or Insurance Company]:

I am writing to appeal the denial of therapy with HAEGARDA® (C1 Esterase Inhibitor Subcutaneous [Human]) for patient, [patient name], dated [date of denial]. HAEGARDA® is approved for routine prophylaxis to prevent Hereditary Angioedema (HAE) attacks in adolescent and adult patients.

[Payer Name] has indicated on the attached [denial letter, EOB, or remittance advice] that [patient name] does not qualify for therapy with HAEGARDA® because [insert reason for denial as specifically stated in attached document]. We disagree with this decision, and ask that this denial be reversed [insert reason why you disagree].

We believe that [patient name’s] therapy is medically appropriate and necessary, and should be a covered service. This letter outlines our patient’s medical history, prognosis, and recaps the rationale for our therapy decision, addressing the specific denial reason cited by [payer name].

**Clinical Justification for Therapy**

[Patient name] was diagnosed with Hereditary Angioedema [insert ICD-10 diagnosis code and Type of HAE] as of [date or age of diagnosis]. Laboratory testing [for Type II, C4, C1-INH antigen and C1-INH or I function] are all consistent with a diagnosis of [Type I or Type II. If Type III insert F12 test results and/or family history.] Hereditary Angioedema. Attached please find the pre-therapy laboratory results.

In terms of the patient’s disease history, [his/her] attacks have typically involved the [insert all that apply: abdomen, extremity, face, larynx, genitalia, other]. Attack frequency is approximately [insert attacks per month or year]. These attacks are debilitating, and have resulted in [insert # of ER visits/time, # of hospitalizations, level of care (ICU if applicable), # of days of hospitalization, and/or intubations if applicable].

[Patient name] has previously been taking [insert prior therapies and results]. [He/She selectas many as apply: is contraindicated for, is intolerant to, and/or has tried and failed] alternative therapies for HAE, including [pick as many as have been tried, and specify why they have not worked: androgens, antifibrinolytics, other C1-INH agents, MABs]. We have ruled out other possible causes of [patient name], symptoms, including [insert all that apply: allergic angioedema and/or medications known to cause angioedema symptoms, eg, ACE inhibitors, estrogens, or Angiotensin II blockers].

Given the patient’s history, condition, and the published data supporting use of HAEGARDA**,** I believe therapy of [patient name]with HAEGARDA is warranted, appropriate and medically necessary. The accompanying package insert provides the approved clinical information for HAEGARDA. Our plan of care is for this patient to take HAEGARDA® at a dose of \_\_\_ units of HAEGARDA subcutaneously twice weekly (every 3 or 4 days). The patient weighs [insert weight in kg], so the total dose per therapy would be [insert total IU’s per dose, # of 2000 or 3000 IU vials per therapy]. The monthly dose would be [insert IU’s per dose, times dose frequency, requiring # of 2000 or 3000 IU vials per therapy]. We plan to [continue other on-demand therapies, discontinue other prophylactic therapies], consistent with the clinical practice guidelines for therapy of such patients.

Based on the information supplied above, we believe that the prior denial of our request for [patient name] therapy with HAEGARDA is inappropriate and not consistent with the standard of care for HAE patients. We trust that the information we have provided above adequately addresses the reason for denial, and provides a rationale for our patient to [start, continue] therapy with HAEGARDA. Therefore, we respectfully request that this denial be overturned, and that [patient name] be allowed to [begin, continue] therapy as soon as possible. Without such therapy, [patient name] will likely [insert concerns about sequelae without therapy].

Please contact my office with your decision no later than 30 days from the date of this letter, as specified under the Affordable Care Act.

Please call my office at [insert telephone number] if I can provide you with any additional information. I look forward to receiving your timely response and approval of this claim.

Sincerely,

[Insert Doctor’s Name]

[Participating Provider ID #]

Enclosure:

FDA Approval Letter

HAEGARDA Prescribing Information