Prepare for writing an effective letter

1. If applicable, get a copy of the denial letter
2. Get a copy of the coverage policy
   a. You can request a copy directly from the health plan
   b. You can access a copy on the health plan's website
   c. You can call HAEGARDA Connect or your old CSL field reimbursement manager and request a copy
3. Compare the patient's test results with the medical coverage criteria

Determine if a letter is needed

1. Was treatment denied because of missing information?
2. Do you have the missing information available?
   a. If you answered yes to both questions, you have the option to resubmit the authorization request with the missing information and request a redetermination instead of an appeal, thus saving an appeal option that may be needed later.

Writing the letter requires 4 basic elements

1. **Be direct and succinct**
   a. Lead with the headline
      i. State your request from the onset. Additionally, give them the diagnosis for which the treatment is HAE up front. If other diagnoses are a contributing factor list those after the primary diagnosis has been stated.
2. **Make it organized**
   a. Explain what medical criteria were used to make the diagnosis
      i. If the criteria don't match the criteria required in the medical coverage policy, explain why the diagnosis is still correct. Remember you are the treating health care provider. This is an opportunity to both educate and change policy if it is incorrect.
3. **Support your request with evidence of the diagnosis**
   a. Provide supporting documentation and reference it in the letter. For example, my patient has a positive______test showing_____. See supporting documentation labeled______.
   b. Rare diseases are not well understood. Therefore, your letter may be better understood with copies of peer reviewed literature and or copies of practice guidelines. Don't be afraid to reference it and or provide a copy to the health plan. You might say, "My treatment plan is supported by_guidelines, a copy of which has been provided.
4. **Close by restating your request and what the consequences are for the patient should they not receive your recommended treatment.**

The following pages contain a suggested format for a coverage denial appeal letter and formulary exception appeal letter. This template is a suggestion only and must be tailored to accurately describe the patient's symptoms and history, as well as those reasons why the product is medically justified for the patient. Not all suggested statements are applicable to all patients. The statements included in these templates are based on a review of coverage policies for many commercial payers, but you are responsible for including information relevant to the coverage/formulary decision made by the patient's insurer and/or PBM. You are further responsible for ensuring that all information submitted to the relevant commercial payer is correct and justified in light of the patient's medical record.

Appeal Letter

[*Insert* physician letterhead]

[*Insert* Name of Medical Director listed on Denial]
[*Insert* Insurance Company]
[*Insert* Address]
[*Insert* City, State, Zip]

RE: [Insert Patient First Name, Middle Initial, Last Name]
DOB: [*Insert* DOB]
Policy #: [*Insert* patient policy #____________________________]
Claim #: [*Insert* claim #]
Subject: Appeal of Denial of Coverage for Hereditary Angioedema (HAE) - HAEGARDA® (C1 Esterase Inhibitor Subcutaneous [Human])

To Whom It May Concern:

I am writing to appeal the denial of therapy with HAEGARDA® (C1 Esterase Inhibitor Subcutaneous [Human]) for patient, [*Insert* Patient Name], dated [*Insert* date of denial]. HAEGARDA® was approved by the U.S. FDA in June 2017, and is approved for routine prophylaxis to prevent Hereditary Angioedema (HAE) attacks in patients 6 years of age and older.

[*Insert* Payer Name] has indicated on the attached denial letter that [*Insert* Patient Name] does not qualify for therapy with HAEGARDA® because [*Insert* reason for denial as specifically stated in attached document]. I disagree with this decision due to [*Insert* reason why you disagree], and ask that this denial be reversed.

I believe that [*Insert* Patient Name] therapy is medically appropriate and necessary and should be a covered service. This letter outlines my patient's medical history, prognosis, and recaps the rationale for my therapy decision, addressing the specific denial reason(s) cited by [*Insert* Payer Name].

Clinical Justification for this Therapy

[*Insert* Patient Name] was diagnosed with Hereditary Angioedema [*Insert* ICD-10 diagnosis code and Type of HAE] as of [*Insert* initial treatment date or age of diagnosis]. Laboratory testing results are as follows: [*Insert* C4 levels, C1-INH antigenic and C1-INH function levels are all consistent with a diagnosis of [*Insert* either Type I or Type II or Type III. Note: If Type III also *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, [*Insert* his or 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].

[*Insert* Patient Name] has previously been taking [*Insert* prior therapies and results]. [*Insert* He or She] 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]. I have ruled out other possible causes of [*Insert* 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 for [*Insert* Patient name] with HAEGARDA is warranted, appropriate and medically necessary. The accompanying package *Insert* provides the approved clinical information for HAEGARDA. My 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 IUs per dose, # of 2000 or 3000 IU vials per therapy]. The monthly dose would be [*Insert* IUs per dose, times dose frequency, requiring # of 2000 or 3000 IU vials per therapy]. I also 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, I believe that the prior denial of this request for [*Insert* Patient Name] therapy with HAEGARDA is inappropriate and not consistent with the standard of care for HAE patients. I trust that the information which I have provided above adequately addresses the reason(s) for denial and provides a rationale for our patient to [start, continue] therapy with HAEGARDA. Therefore, I respectfully request that this denial be overturned quickly, and that [*Insert* Patient Name] be allowed to [begin, continue] therapy as soon as possible. Without such therapy, this patient 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 #]

Enclosures:
Denial Letter
Lab Results
Patient Medical Records
FDA Approval Letter
HAEGARDA Prescribing Information