**Letter of Medication/Formulary Exception**

***[Include on office letterhead)***

[DATE]

[PAYER NAME]

[PAYER ADDRESS]

Attn: [APPEALS DEPARTMENT]

Re: [PATIENT NAME]

[POLICY ID/GROUP NUMBER]

Dear [INSERT CONTACT]:

I am writing to request that a formulary exception be granted for [PATIENT NAME], who has been prescribed HAEGARDA®, C1 Esterase Inhibitor Subcutaneous (Human) and has been diagnosed with Hereditary Angioedema (HAE). HAEGARDA® is indicated for routine prophylaxis to prevent Hereditary Angioedema (HAE) attacks in adolescent and adult patients.

[PAYER NAME]

does not include HAEGARDA® on the approved formulary list

requires prior failure on [list agents] before the patient can receive HAEGARDA

In my clinical judgment and considering [PATIENT’S NAME] history of illness, therapy with HAEGARDA® is appropriate and medically necessary in order to manage this patient’s illness.

Clinical justification for HAEGARDA use versus androgens[[1]](#endnote-1) or antifibrinolytics[[2]](#endnote-2) (eg, danazol or tranexamic acid):

inadequate treatment response  intolerance  contraindication

[PATIENT NAME] is contraindicated for the use of androgens or antifibrinolytics because they are:

< 16 years of age

Of childbearing age (currently pregnant or may become pregnant)

Breastfeeding

Thrombophilia, increased thrombotic risk, or acute thrombosis, (eg, DVT or PE)

Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[PATIENT NAME] is intolerant to the use of androgens or antifibrinolytics because they have:

Markedly impaired hepatic, renal, or cardiac function

Porphyria

Androgen-dependent tumor

Active thrombosis or history of thromboembolic disease

Undiagnosed abnormal genital bleeding

Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I have enclosed additional documentation that supports therapy with HAEGARDA®. I would appreciate your immediate review and approval for a formulary exception. If you have any questions or need additional information, please contact me at [HCP PHONE NUMBER] to discuss further. Thank you for your immediate attention to this request.

Sincerely,

[HCP FIRST NAME LAST NAME, [SUFFIX]

1. Zuraw BL, Banerji A, Bernstein JA, et al. US Hereditary Angioedema Association Medical Advisory Board 2013 recommendations for the management of hereditary angioedema due to C1 inhibitor deficiency. *J Allergy Clinical Immunol*: *In Practice*. 2013; 1(5): 458-467.

   *Per the 2013 US HAEA clinical practice guidelines,* ***page 463, section 3.4: “Special considerations in the use of androgens. Although anabolic androgens (17-alpha-alkylated androgens) have been successfully used for prophylaxis for many years, they can cause dose-related side effects that may be significant. It is important to avoid the use of anabolic androgens for long-term prophylaxis in patients under the age of 16 years or in pregnant or breastfeeding women. The use of anabolic androgens should also be avoided when the patient does not tolerate them or in patients who experience troubling adverse effects.*** *It is the position of the HAEA MAB that these medications should not be used in patients who express a preference for an alternative therapy and that patients should not be required to fail androgen therapy as a prerequisite to receiving prophylactic C1INH concentrate.”*

   [↑](#endnote-ref-1)
2. Maurer, M, Mageral M, Ansotegui I, et al. The international WAO/EAACI guideline for the management of hereditary angioedema–the 2017 revision and update. *World Allergy Organization Journal*. 2018;11(5):1-20.

   **Use of Antifibrinolytics per the 2017 WAO Clinical Practice Guidelines: Page 10***, “Antifibrinolytics are not recommended for long-term prophylaxis. Data for their efficacy are largely lacking, but some patients may find them helpful. They are primarily used when C1-INH concentrate is not available and androgens are contraindicated.”* **Page 11,** *“When C1-INH concentrate is not available for long-term prophylaxis, antifibrinolytics (ie, Tranexamic acid 10-40 mg/kg) are preferred to androgens because of their better safety profile; however, efficacy is questioned by many, and data are not available supporting its use.”* Antifibrinolytics are also not indicated for the treatment of HAE.

   **Use of Androgens per the 2017 WAO Clinical Practice Guidelines: page 10, *Recommendation 10:*** *The WAO recommends the “use of C1-INH therapy for first-line long-term prophylaxis.”* ***Recommendation 11:*** *The WAO recommends “androgens as second-line long-term prophylaxis”* ***page 12:*** *“C-1 INH concentrate is recommended as first-line therapy for pregnant or breastfeeding HAE-1/2 patients as it is safe and effective.”*

   HGD-0589-FEB19 [↑](#endnote-ref-2)