

**Hemophilia Non-Factor Products Prior Authorization Form**

**Member Name:** \_\_\_\_\_ **Date of Birth:** \_\_\_\_\_ **Member ID#:** \_\_\_\_\_

**Drug Information**

**Physician billing (HCPCS code: \_\_\_\_\_)**  **Pharmacy billing (NDC: \_\_\_\_\_)**

**Name of Medication:** \_\_\_\_\_ **Start Date (or date of next dose):** \_\_\_\_\_

**Dose:** \_\_\_\_\_ **Regimen:** \_\_\_\_\_

**Billing Provider Information**

**Provider NPI:** \_\_\_\_\_ **Provider Name:** \_\_\_\_\_

**Provider Phone:** \_\_\_\_\_ **Provider Fax:** \_\_\_\_\_

**If pharmacy billing, Pharmacist name:** \_\_\_\_\_

**Prescriber Information**

**Prescriber NPI:** \_\_\_\_\_ **Prescriber Name:** \_\_\_\_\_

**Prescriber Phone:** \_\_\_\_\_ **Prescriber Fax:** \_\_\_\_\_ **Specialty:** \_\_\_\_\_

**Criteria**

**For Initial Authorization:**

1. Diagnosis (ICD-10): \_\_\_\_\_ Inhibitor: Yes \_\_\_ No \_\_\_
2. Is prescriber a hematologist specializing in rare bleeding disorders or practicing in a federally recognized Hemophilia Treatment Center (HTC) or mid-level practitioner under the supervision of a physician at an HTC? Yes \_\_\_ No \_\_\_
3. Member's weight: \_\_\_\_\_ (kg); Date taken: \_\_\_\_\_
4. Does the prescriber attest that the member will not be continuing other prophylactic therapies for Alhemo<sup>®</sup>, Hemlibra<sup>®</sup> and Hympavzi<sup>®</sup>, or longer than 7 days for Qfitlia<sup>™</sup>? Yes \_\_\_ No \_\_\_
5. For **Alhemo<sup>®</sup>**:
  - a. Does the member have severe Hemophilia A without inhibitors or moderately severe to severe Hemophilia B? Yes \_\_\_ No \_\_\_
  - b. For members without an inhibitor please provide a clinically significant reason why the member's current prophylaxis therapy is not appropriate: \_\_\_\_\_
  - c. Is member undergoing immune tolerance induction? Yes \_\_\_ No \_\_\_
  - d. Does the member have a history of or is at high risk for thromboembolic events? Yes \_\_\_ No \_\_\_
  - e. For females of reproductive potential:
    - i. Is member pregnant? Yes \_\_\_ No \_\_\_
      - A. If yes, or if member becomes pregnant during treatment, will the risk to the fetus be weighed against the benefit to the mother? Yes \_\_\_ No \_\_\_
    - ii. Does the member agree to use effective birth control during treatment and for at least 7 weeks after the last dose? Yes \_\_\_ No \_\_\_

**(Alhemo<sup>®</sup> continued on next page)**

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**Hemophilia Non-Factor Products Prior Authorization Form**

**Member Name:** \_\_\_\_\_ **Date of Birth:** \_\_\_\_\_ **Member ID#:** \_\_\_\_\_

**Criteria**

**For Initial Authorization: (continued)**

**5. For Alhemo®: (continued from Page 1)**

- f. Has the member or caregiver been trained on the subcutaneous administration and storage of Alhemo®?  
Yes \_\_\_ No \_\_\_
- g. Has the member been counseled on the potential risk of thrombosis and use of bypassing agents or factor concentrate at the lowest possible dose for breakthrough bleeding episodes based on severity and location of bleed? Yes \_\_\_ No \_\_\_

**6. For Hemlibra®:**

- a. Will prescriber monitor appropriate blood clotting tests and levels utilizing testing which accounts for the interaction of Hemlibra® and blood factors by following the Medical and Scientific Advisory Council (MASAC) guidance? Yes \_\_\_ No \_\_\_
- b. Will a treatment plan be developed to address breakthrough bleeds and procedures? Yes \_\_\_ No \_\_\_
- c. Location where first dose will be given: \_\_\_\_\_

**d. For members with an inhibitor to factor VIII:**

- i. Will member be using Feiba® for breakthrough bleeding? Yes \_\_\_ No \_\_\_
  - 1. If yes, has member/caregiver been counseled on the risks of using Feiba® while taking Hemlibra®? Yes \_\_\_ No \_\_\_
- ii. Will member be closely monitored if any bypassing agent is given? Yes \_\_\_ No \_\_\_

**e. For members without an inhibitor:**

- i. Does the member have severe hemophilia A or moderate hemophilia A presenting as severe?  
Yes \_\_\_ No \_\_\_
- ii. Does prescriber agree to perform routine lab screening for factor VIII inhibitor while using Hemlibra®?  
Yes \_\_\_ No \_\_\_

f. Hemlibra® dose prescribed: \_\_\_\_\_ Regimen: \_\_\_\_\_  
 NDCs: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ vials per dose: \_\_\_\_\_      \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ vials per dose: \_\_\_\_\_  
 NDCs: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ vials per dose: \_\_\_\_\_      \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ vials per dose: \_\_\_\_\_

**7. For Hympavzi®:**

- a. Does the member have moderately severe to severe Hemophilia A or Hemophilia B without inhibitors?  
Yes \_\_\_ No \_\_\_
- b. Does the member have a current inhibitor or documented history of an inhibitor? Yes \_\_\_ No \_\_\_
- c. For females of reproductive potential:
  - i. Is member pregnant? Yes \_\_\_ No \_\_\_
  - ii. Will member have a negative pregnancy test prior to therapy initiation? Yes \_\_\_ No \_\_\_
  - iii. Is member willing to use effective contraception during and after treatment for at least 2 months after the last dose? Yes \_\_\_ No \_\_\_

**(Hympavzi® continued on next page)**

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**Hemophilia Non-Factor Products Prior Authorization Form****Member Name:** \_\_\_\_\_ **Date of Birth:** \_\_\_\_\_ **Member ID#:** \_\_\_\_\_**Criteria****For Initial Authorization:** *(continued)***7. For Hympavzi<sup>®</sup>:** *(continued from Page 2)*

- d. Does member have uncontrolled human immunodeficiency virus (HIV) as shown by CD4+ counts  $\leq 200$  cells/mm<sup>3</sup>? Yes \_\_\_ No \_\_\_
- e. Has the member or caregiver been trained on the subcutaneous administration and storage of Hympavzi<sup>®</sup>? Yes \_\_\_ No \_\_\_
- f. Has the member been counseled on the use of factor replacement therapy at the lowest possible dose for breakthrough bleeding episodes? Yes \_\_\_ No \_\_\_
- g. Requests for 300mg weekly:
  - i. Does the member weigh  $\geq 50$ kg? Yes \_\_\_ No \_\_\_
  - ii. Has the member had  $\geq 2$  spontaneous bleeding episodes which were treated with factor replacement therapy in the last 6 months despite compliance? Yes \_\_\_ No \_\_\_
  - iii. Has the member developed inhibitors? Yes \_\_\_ No \_\_\_

**8. For Qfitlia<sup>™</sup>:**

- a. Does the member have severe hemophilia A or B? Yes \_\_\_ No \_\_\_
- b. Does the member have a history of or is at high risk for thromboembolic events? Yes \_\_\_ No \_\_\_
- c. Does the member have clinically significant liver disease? Yes \_\_\_ No \_\_\_
- d. Does the member have active hepatitis C? Yes \_\_\_ No \_\_\_
- e. Does the member have an acute or chronic hepatitis B infection? Yes \_\_\_ No \_\_\_
- f. Does member have uncontrolled human immunodeficiency virus (HIV) as shown by CD4+ counts  $\leq 200$  cells/mm<sup>3</sup> or viral load  $\geq 20$  copies/mL? Yes \_\_\_ No \_\_\_
- g. Does the member have a history of symptomatic gallbladder disease? Yes \_\_\_ No \_\_\_
  - i. If yes, please provide a reason why the member cannot use other available treatments:  
\_\_\_\_\_
- h. Does prescriber agree to perform and FDA-cleared test for antithrombin activity at weeks 4, 12, 20, and 24 and adjust the dosing as outlined in package labeling? Yes \_\_\_ No \_\_\_
- i. Does prescriber agree to perform baseline liver tests prior to initiation of fitusiran and monthly for at least 6 months and after any dose increase? Yes \_\_\_ No \_\_\_
- j. Has the member or caregiver been trained on the subcutaneous administration and counseled on the storage of fitusiran? Yes \_\_\_ No \_\_\_
- k. Has the member been counseled on the use of factor replacement therapy or bypassing agent as outlined in the prescribing information for breakthrough bleeding episodes? Yes \_\_\_ No \_\_\_

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**Member Name:** \_\_\_\_\_ **Date of Birth:** \_\_\_\_\_ **Member ID#:** \_\_\_\_\_

**Criteria**

**For Continued Authorization:**

1. Date of last dose: \_\_\_\_\_
2. Member's weight: \_\_\_\_\_ (kg); Date taken: \_\_\_\_\_
3. Has the member experienced any adverse drug reactions related to therapy? Yes \_\_\_ No \_\_\_
  - a. If yes, please specify adverse reactions: \_\_\_\_\_
3. Please provide documentation of clinical effectiveness:
   
\_\_\_\_\_
   
\_\_\_\_\_
   
\_\_\_\_\_
4. For Hemlibra<sup>®</sup>, has there been a decrease in the number of spontaneous bleeding episodes since beginning Hemlibra<sup>®</sup> treatment? Yes \_\_\_ No \_\_\_

**Additional Information:** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Prescriber Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Pharmacist Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

*Please do not send in chart notes. Specific information/documentation will be requested if necessary. Failure to complete this form in full will result in processing delays.*

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