# SENTARA HEALTH PLANS

## PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

**Directions**: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

**Drug Requested: Qfitlia™** (fitusiran)

**MEMBER & PRESCRIBER INFORMATION:** Authorization may be delayed if incomplete.

**Member Name:** _____

**Member Sentara #:** _____ **Date of Birth:** _____

**Prescriber Name:** _____

**Prescriber Signature:** _____ **Date:** _____

**Office Contact Name:** _____

**Phone Number:** _____ **Fax Number:** _____

**NPI #:** _____

**DRUG INFORMATION:** Authorization may be delayed if incomplete.

**Drug Name/Form/Strength:** _____

**Dosing Schedule**: _____ **Length of Therapy**: _____

**Diagnosis:** _____ **ICD Code, if applicable:** _____

**Weight (if applicable):** _____ **Date weight obtained:** _____

**Quantity Limits:** 1 vial or pen per 28 days

- 20 mg/0.2 mL vial
- 50 mg/0.5 mL prefilled auto-injector pen

**CLINICAL CRITERIA:** Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

**Initial Authorization: 6 months**

- ❑ Member is at least 12 years of age
- ❑ Medication prescribed by a specialist familiar with treating patients with hemophilia (factor VIII or IX deficiency)

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- ❑ Provider has measured the member's antithrombin (AT) activity level, and has submitted laboratory documentation confirming level is ≥ 60% prior to start of therapy and AT-activity will be monitored periodically, as outlined in the prescribing information, throughout therapy
- ❑ Member does **NOT** have hepatic impairment (Child-Pugh Class A, B and C)
- ❑ Member does **NOT** have a co-existing thrombophilic disorder or a history of, or risk factors predisposing to, thrombosis
- ❑ Member does **NOT** have a co-existing a history of symptomatic gallbladder disease, or interruption/discontinuation of therapy in patients with acute/recurrent gallbladder disease
- ❑ Requested medication fitusiran will **NOT** be used in combination with hemophilia bypassing agent prophylaxis (i.e., factor VIIa or anti-inhibitor coagulant complex), immune tolerance induction with clotting factor products (i.e., factor VIII or factor IX concentrates) as prophylactic therapy, Hemlibra® (emicizumab-kxwh) in those with hemophilia A as prophylactic therapy, and Hympavzi® (marstacimab-hncq) or Alhemo® (concizumab-mtci) in those with hemophilia A or hemophilia B as prophylactic therapy
- ❑ Member meets **ONE** of the following diagnosis conditions:
  - ❑ Member has a diagnosis of **Hemophilia A** (congenital factor VIII deficiency) and meets **ALL** the following:
    - ❑ Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing
    - ❑ A level of severe hemophilia A is documented by a factor VIII activity level < 1 IU/dL (in the absence of exogenous factor VIII)
    - ❑ Member has **NOT** received prior gene therapy for hemophilia A (e.g., Roctavian® (valoctocogene roxaparvovec-rvox))
    - ❑ Provider will **NOT** plan to use fitusiran as combination therapy with a hemophilia bypassing agent (i.e., factor VIIa or anti-inhibitor coagulant complex such as Sevenfact) or an FVIII clotting factor concentrate such as Wilate, Novoeight, Adynovate, Altuviiio, etc.

      **NOTE:** Members may continue their prior clotting factor concentrates (CFC) or bypassing agent (BPA) prophylaxis for the first 7 days of fitusiran treatment. Discontinue any CFC or BPA prophylaxis no later than 7 days after the initial dose of Qfitlia. Any authorization approval on record will be termed.
    - ❑ Member meets **ONE** of the following:
      - ❑ Member has a history of life-threatening hemorrhage requiring on-demand use of factor replacement therapy
      - ❑ Member has a history of repeated, serious spontaneous bleeding episodes requiring on-demand use of Factor VIII therapy was required for these serious spontaneous bleeding episodes

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- ❑ Member has a diagnosis of **Hemophilia B** (congenital factor IX deficiency) and meets **ALL** the following:
  - ❑ Diagnosis of congenital factor IX deficiency has been confirmed by blood coagulation testing
  - ❑ A level of severe hemophilia B is documented by a factor IX activity level ≤ 2 IU/dL (in the absence of exogenous factor IX)
  - ❑ Member has **NOT** received prior gene therapy for hemophilia B (e.g., Hemgenix® (etranacogene dezaparvovec-drlb), Beqvez™ (fidanacogene elaparvovec-dzkt))
  - ❑ Provider will **NOT** plan to use fitusiran as combination therapy with a hemophilia bypassing agent (i.e., factor VIIa or anti-inhibitor coagulant complex such as Sevenfact) or an FIX clotting factor concentrate such as AlphaNine, BeneFIX, etc.

    **NOTE:** Members may continue their prior clotting factor concentrates (CFC) or bypassing agent (BPA) prophylaxis for the first 7 days of fitusiran treatment. Discontinue any CFC or BPA prophylaxis no later than 7 days after the initial dose of Qfitlia. Any authorization approval on record will be termed.
  - ❑ Member meets **ONE** of the following:
    - ❑ Member has a history of life-threatening hemorrhage requiring on-demand use of factor replacement therapy
    - ❑ Member has a history of repeated, serious spontaneous bleeding episodes requiring on-demand use of Factor IX therapy was required for these serious spontaneous bleeding episodes

**Reauthorization: 12 months.** All criteria that apply must be checked for approval. To support each line checked, all documentation (lab results, diagnostics, and/or chart notes) must be provided or request may be denied.

- ❑ Member continues to meet the indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, precluding medical conditions, etc., identified in the initial authorization section
- ❑ Member has **NOT** experienced any unacceptable toxicity from the drug (severe hepatotoxicity, thromboembolic events, severe gallbladder disease, etc.)
- ❑ Member has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline, in severity of bleeding episodes, and/or in the number of spontaneous bleeding events)

  **NOTE:** Providers must submit well-documented, quantitative assessment of bleeding events since initiating

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- ❑ Provider has monitored AT-activity, and has submitted laboratory documentation to confirm **ONE** of the following:
  - ❑ Member's AT-activity is less than 15% **AND** the provider will reduce dose of fitusiran according to package labeling

    **NOTE:** Members who were receiving a dose of 10mg every 2 month must discontinue therapy
  - ❑ Member's AT-activity is 15% - 35% **AND** the provider will continue on established dose of fitusiran according to package labeling

    **NOTE:** No increase in dosage will be approved
  - ❑ Member's AT-activity is >35% after 6 months **AND** has **NOT** achieved satisfactory bleed control compared to baseline; provider can escalate the dosing administration frequency to every month

**Medication being provided by Specialty Pharmacy – Proprium Rx**

***Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.***

**Previous therapies will be verified through pharmacy paid claims or submitted chart notes.***