SENTARA HEALTH PLANS

MEDICAL 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 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Qfitlia™ (fitusiran) (J3490) (Medical)

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:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Dosing Limits:

A. Quantity Limit (max daily dose) [NDC Unit]:
- 1 vial or prefilled auto-injector pen once per month
- NDC:
  - Qfitlia 50 mg single-dose (50 mg/0.5 mL) prefilled pen: 58468-0348-xx
  - Qfitlia 20 mg (20 mg/0.2 mL) single-dose vial: 58468-0347-xx

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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)
- ❑ 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.

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- ❑ 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
- ❑ 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 (check applicable box(es) below):

❑ **Physician's office** **OR** ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

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.