RX.PA.113.MPC QFITLIA (fitusiran)

PURPOSE

The purpose of this policy is to define the prior authorization process for Qfitlia™ (fitusiran).

Qfitlia™ (fitusiran) is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with:

- Hemophilia A (congenital factor VIII deficiency)
- Hemophilia B (congenital factor IX deficiency)
  - With or without FVIII or FIX inhibitors.

Severity	Clotting factor level % activity	Bleeding Episodes
Severe	< 1%	Spontaneous bleeding episodes, predominantly into joints and muscles Severe bleeding with trauma, injury or surgery
Moderate	1% to 5%	Occasional spontaneous bleeding episodes Severe bleeding with trauma, injury or surgery
Mild	6% to 40%	Severe bleeding with serious injury, trauma or surgery

PROCEDURE

A. Initial Authorization Criteria

1. Hemophilia A or B with or without factor VIII or IX inhibitors:
Must meet all the criteria listed. Approve for 3 months if the patient meets criteria.

- Patient is ≥ 12 years of age

- Patient has a documented diagnosis of severe Hemophilia A (congenital factor VIII deficiency) or Hemophilia B (congenital factor IX deficiency aka Christmas Disease) as confirmed by blood coagulation testing
    - [Note: Severity defined as a FVIII level < 1% or FIX level ≤ 2%]
- Patient must have at least 6 documented bleeding episodes requiring factor concentrate treatment within the last 12 months prior to this request
- Must be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
    - Provider attests that Qfitlia will not be used for the treatment of breakthrough *bleeds*
- Patient does not have a co-existing thrombophilic disorder or a history of, or risk factors predisposing to, thrombosis
- Patient has documentation of antithrombin (AT) activity level of ≥ 60% prior to start of therapy and AT-activity will be monitored periodically, as outlined in the prescribing information, throughout therapy
- Patient does not have hepatic impairment (Child-Pugh Class A, B or C)
- Must not be concurrently using with Alhemo (concizumab-mtci subcutaneous injection), Hemlibra (emicizumab-kxwh subcutaneous injection), or Hympavzi (marstacimab-hncq subcutaneous injection).
- Will NOT be used in combination with any of the following
    - (Note: Patients may continue their prior clotting factor concentrates (CFC) or bypassing agent (BPA) prophylaxis for the first 7 days of Qfitlia treatment. CFC or BPA prophylaxis must be discontinued no later than 7 days after the initial dose of Qfitlia):
      Hemophilia bypassing agent prophylaxis (i.e., factor VIIa or anti-inhibitor coagulant complex); OR o Immune tolerance induction with clotting factor products (i.e., factor VIII or factor IX concentrates) as prophylactic therapy;

B. <u>Reauthorization Criteria:</u>

<u>MPC Renewal:</u> Approve for 1 year if the patient meets ALL the following:

- Patient is using Qfitlia for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
- According to the prescriber, prophylactic use of Factor VIII products will not occur while receiving Qfitlia
- The medication is prescribed by or in consultation with a hematologist; AND
- According to the prescriber, the patient experienced a beneficial response to therapy.

  - Note: Examples of a beneficial response to therapy include a reduction in bleeding events, in the severity of bleeding episodes, in the number of bleeding events that required treatment, and/or in the number of spontaneous bleeds.
- Must not be concurrently using with Alhemo (concizumab-mtci subcutaneous injection), Hemlibra (emicizumab-kxwh subcutaneous injection), or Hympavzi (marstacimab-hncq subcutaneous injection).

OR

Renewal from Previous Insurer:

- Members who have received prior approval (from insurer other than MPC), or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria)
- According to the prescriber, the patient experienced a beneficial response to therapy.

C. Qfitlia will be considered investigational or experimental for any other use and will not be covered.

Dosing Table	
Initial	• **50 mg every 2 months**
Maintenance (dosing adjustments based on antithrombin activity between 15% and 35%)	• **50 mg every 2 months or** • **20 mg every 2 months or** • **10 mg every 2 months**

Note: The dose and/or dosing interval should be individually adjusted if needed to maintain antithrombin activity level between 15% and 35. Any measures of antithrombin activity level < 15% requires a dose reduction, with the lower dose initiated 3 months after the prior dose. A dose escalation should be considered if an antithrombin activity level is > 35% after 6 months or if the patient has not achieved satisfactory bleed control

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months
Reauthorization	Up to 1 year

APPLICABLE CODES:	
CODE	**DESCRIPTION**
J3490	Unclassified drugs

REFERENCES

1. Qfitlia™ subcutaneous injection [prescribing information]. Cambridge, MA: Genzyme/Sanofi; March 2025.
2. Franchini M, Mannucci PM. The more recent history of hemophilia treatment. Semin
3. National Bleeding Disorders Foundation. Hemophilia A: An overview of symptoms, genetics, and treatments to help you understand hemophilia A. Available at: https://www.bleeding.org/bleedingdisorders-a-z/types/hemophilia-a.
4. National Hemophilia Foundation. Hemophilia B. An overview of symptoms, genetics, and treatments to help you understand hemophilia B. Available at: https://www.hemophilia.org/bleeding-disorders-a-z/types/hemophilia-b.

Review History

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	02/2026
New policy	08/2025