UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2372-2
Program	Prior Authorization/Medical Necessity
Medication	Qfitlia® (fitusiran)
P&T Approval Date	5/2025, 8/2025
Effective Date	10/1/2025

1. Background:

Qfitlia (fitusiran) is an antithrombin-directed small interfering ribonucleic acid indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients aged 12 years and older with hemophilia A or B with or without factor VIII or IX inhibitors.

2. Coverage Criteria[a]:

A. Hemophilia A With Inhibitors

1. **Initial Authorization**

a. **Qfitlia** will be approved based on **all** of the following criteria

(1) **Both** of the following:

(a) Diagnosis of hemophilia A

-AND-

(b) Patient has developed high-titer factor VIII inhibitors (i.e., patient has developed factor VIII inhibitors greater than or equal to 5 Bethesda units [BU])

-AND-

(2) Patient is 12 years of age or older

-AND-

(3) Prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Documentation of positive clinical response to Qfitlia therapy

Authorization will be issued for 12 months.

B. Hemophilia A Without Inhibitors

1. **Initial Authorization**

a. **Qfitlia** will be approved based on **all** of the following criteria

(1) **Both** of the following:

(a) Diagnosis of hemophilia A

-AND-

(b) Patient has not developed high-titer factor VIII inhibitors (i.e., patient has NOT developed factor VIII inhibitors greater than or equal to 5 Bethesda units [BU])

-AND-

(2) Patient is 12 years of age or older

-AND-

(3) Qfitlia is prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

-AND-

(4) **One** of the following:

(a) Based on clinical patient assessment, the provider has determined that the patient is not an appropriate candidate for Hympavzi (document reason)

-OR-

(b) Both of the following:

i. Patient is currently on Qfitlia therapy

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the HemAssist or Sanofi Patient Support (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of **Qfitlia***

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from

the HemAssist or Sanofi Patient Support **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Qfitlia** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Qfitlia therapy

Authorization will be issued for 12 months.

C. Hemophilia B With Inhibitors

1. **Initial Authorization**

a. **Qfitlia** will be approved based on **all** of the following criteria

(1) **Both** of the following:

(a) Diagnosis of hemophilia B

-AND-

(b) Patient has developed high-titer factor IX inhibitors (i.e., patient has developed factor IX inhibitors greater than or equal to 5 Bethesda units [BU])

-AND-

(2) Patient is 12 years of age or older

-AND-

(3) Prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Documentation of positive clinical response to Qfitlia therapy

Authorization will be issued for 12 months.

D. Hemophilia B Without Inhibitors

1. **Initial Authorization**

a. **Qfitlia** will be approved based on **all** of the following criteria

(1) **Both** of the following:

(a) Diagnosis of hemophilia B

-AND-

(b) Patient has not developed high-titer factor IX inhibitors (i.e., patient has NOT developed factor IX inhibitors greater than or equal to 5 Bethesda units [BU])

-AND-

(2) Patient is 12 years of age or older

-AND-

(3) Qfitlia is prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

-AND-

(4) **One** of the following:

(a) Based on clinical patient assessment, the provider has determined that the patient is not an appropriate candidate for Hympavzi (document reason)

-OR-

(b) **Both** of the following:

i. Patient is currently on Qfitlia therapy

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the HemAssist or Sanofi Patient Support (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of **Qfitlia***

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the HemAssist or Sanofi Patient Support **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Qfitlia** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Qfitlia therapy **Authorization will be issued for 12 months.**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Qfitlia® [package insert]. Cambridge, MA: Genzyme Corporation; March 2025.
2. Young G, Srivastava A, Kavakli K, et al. Efficacy and safety of fitusiran prophylaxis in people with haemophilia A or haemophilia B with inhibitors (ATLAS-INH): a multicentre, open-label, randomised phase 3 trial. *Lancet*. 2023;401(10386):1427-1437. doi:10.1016/S0140-6736(23)00284-2
3. Srivastava A, Rangarajan S, Kavakli K, et al. Fitusiran prophylaxis in people with severe haemophilia A or haemophilia B without inhibitors (ATLAS-A/B): a multicentre, open-label, randomised, phase 3 trial. *Lancet Haematol*. 2023;10(5):e322-e332. doi:10.1016/S2352-3026(23)00037-6

Program	Prior Authorization/Medical Necessity - Qfitlia (fitusiran)
Change Control	
5/2025	New program
8/2025	Removed criteria of failure to meet clinical goals after a trial of prophylactic factor replacement products. Added preferred therapy criteria for hemophilia A or B without inhibitors. Clarified high titer inhibitor criteria.