UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2372-1
Program	Prior Authorization/Medical Necessity
Medication	Qfitlia® (fitusiran)
P&T Approval Date	5/2025
Effective Date	7/1/2025

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) Diagnosis of hemophilia A

-AND-

(2) Patient has developed high-titer factor VIII inhibitors (≥ 5 Bethesda units [BU])

-AND-

(3) Patient is 12 years of age or older

-AND-

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

Authorization of therapy 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) **One** of the following:

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

i. Diagnosis of severe hemophilia A

-AND-

ii. Documentation of endogenous factor VIII levels less than 1% of normal factor VIII (< 0.01 IU/mL)

-OR-

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

i. **One** of the following

1. **Both** of the following

a. Diagnosis of moderate hemophilia A

-AND-

b. Documentation of endogenous factor VIII level ≥1% < 5% (greater than or equal to 0.01 IU/mL to less than 0.05 IU/mL)

-OR-

2. **Both** of the following

a. Diagnosis of mild hemophilia A

-AND-

b. Documentation of endogenous factor VIII level ≥ 5% (greater than or equal to 0.05 IU/mL)

-AND-

ii. Submission of medical records (e.g., chart notes, laboratory values) documenting a failure to meet clinical goals (e.g., continuation of spontaneous bleeds, inability to achieve appropriate trough level, previous history of inhibitors) after a trial of prophylactic factor VIII replacement products

-OR-

(c) **All** of the following:

i. Patient is currently on Qfitlia therapy

-AND-

ii. Diagnosis of hemophilia A

-AND-

iii. 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***

-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)

* 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 of therapy 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) Diagnosis of hemophilia B

-AND-

(2) Patient has developed high-titer factor IX inhibitors (≥ 5 Bethesda units [BU])

-AND-

(3) Patient is 12 years of age or older

-AND-

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

Authorization of therapy 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) **One** of the following:

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

i. Diagnosis of severe hemophilia B

-AND-

ii. Documentation of endogenous factor IX levels less than 1% of normal factor IX (< 0.01 IU/mL)

-OR-

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

i. **One** of the following

1. **Both** of the following

a. Diagnosis of moderate hemophilia B

-AND-

b. Documentation of endogenous factor IX level ≥1% < 5% (greater than or equal to 0.01 IU/mL to less than 0.05 IU/mL)

-OR-

2. **Both** of the following

a. Diagnosis of mild hemophilia B

-AND-

b. Documentation of endogenous factor IX level ≥ 5% (greater than or equal to 0.05 IU/mL)

-AND-

ii. Submission of medical records (e.g., chart notes, laboratory values) documenting a failure to meet clinical goals (e.g., continuation of spontaneous bleeds, inability to achieve appropriate trough level, previous history of inhibitors) after a trial of prophylactic factor IX replacement products

-OR-

(c) **All** of the following:

i. Patient is currently on Qfitlia therapy

-AND-

ii. Diagnosis of hemophilia B

-AND-

iii. 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***

-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)

* 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 of therapy 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