UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 3195-1
Program	Step Therapy
Medication	Qfitlia® (fitusiran)
P&T Approval Date	8/2025
Effective Date	10/1/2025

1. Background:

Step therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member with hemophilia A or B without inhibitors to try Hympavzi (marstacimab-hncq) before providing coverage for Qfitlia (fitusiran) unless the provider has determined that the patient is not an appropriate candidate for Hympavzi.

Qfitlia 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.

Hympavzi is a tissue factor pathway inhibitor (TFPI) antagonist 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) without factor VIII inhibitors
- hemophilia B (congenital factor IX deficiency) without factor IX inhibitors

2. Coverage Criteria[a]:

A. Hemophilia A Without Inhibitors

1. **Qfitlia** will be approved based on **one** of the following criteria

   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:

      (1) Patient is currently on Qfitlia therapy

      -AND-

      (2) 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.

B. Hemophilia B Without Inhibitors

1. **Qfitlia** will be approved based on **one** of the following criteria

   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:

      (1) Patient is currently on Qfitlia therapy

      -AND-

      (2) 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.

C. Other Indications

1. **Qfitlia** will be approved

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.

- Medical Necessity, Supply limits and/or Notification may be in place.

4. References:

1. Qfitlia® [package insert]. Cambridge, MA: Genzyme Corporation; March 2025.
2. Hympavzi™ [package insert]. New York, NY: Pfizer Inc., October 2024.

Program	Step Therapy - Qfitlia (fitusiran)
Change Control	
Date	Change
8/2025	New program.