Mass General Brigham
Health Plan

Anti Hemophilia Agents
Qfitlia (fitusiran)
Effective 11/17/2025

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	These medications are also available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria. Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview
Qfitlia is a first-in class double stranded small interfering ribonucleic acid (siRNA) for the treatment of hemophilia A and B. Qfitlia was approved with a broad indication to treat adult and pediatric patients 12 years of age or older with hemophilia A or B, with or without inhibitors.

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met:
Severe Hemophilia A with or without inhibitors

1. Diagnosis of severe hemophilia A (FVIII activity level ≤ 1 IU/dL or 1%)
2. Prescriber is a hematologist or consult notes from a hematologist are provided
3. Member is ≥ 12 years of age
4. ONE of the following:
    a. If member has already initiated therapy, results (within the last year) of the antithrombin activity are within the range of 15-35%
    b. Results from FDA-cleared test (ex. INNOVANCE antithrombin assay) to confirm antithrombin activity is > 60% prior to initiating therapy
5. Member has not received any prior gene therapy for hemophilia A
6. Attestation that the member will not be receiving other hemophilia A prophylaxis (e.g., FVIII products, Hemlibra, Hympavzi, Alhemo or bypassing agents) in conjunction with Qfitlia
7. Inadequate response, adverse reaction, or contraindication to Hemlibra
8. Baseline ABR
9. Appropriate dosing

Moderately severe to severe Hemophilia B with or without inhibitors

1. Diagnosis of moderately severe to severe hemophilia B (FIX activity level ≤ 2 IU/dL or 2%)
2. Prescriber is a hematologist or consult notes from a hematologist are provided
3. Member is ≥ 12 years of age
4. ONE of the following:
    a. If member has already initiated therapy, results (within the last year) of the antithrombin activity are within the range of 15-35%
    b. Results from FDA-cleared test (ex. INNOVANCE antithrombin assay) to confirm antithrombin activity is > 60% prior to initiating therapy
5. Member has not received any prior gene therapy for hemophilia B
6. Attestation that the member will not be receiving other hemophilia B prophylaxis (e.g., FIX products, Hympavzi, Alhemo, or bypassing agents) in conjunction with Qfitlia
7. Inadequate response, adverse reaction, or contraindication to ONE of the following:
    a. FIX product for members without inhibitors
    b. Bypassing agent for members with inhibitors
8. Baseline ABR
9. Appropriate dosing

Continuation of Therapy

Prescriber provides documentation of ALL of the following:

1. Most recent antithrombin activity level is between 15% to 35% (dated within 365 days)
2. Decrease in the member's ABR is maintained compared to baseline at the prescribed maintenance dose. Appropriate dosing

Limitations

1. Initial approvals will be granted for 6 months
2. Reauthorizations will be granted for 12 months

References

1. Qfitlia [package insert]. Cambridge (MA): Sanofi.; March 2025.
2. Sanofi. Mechanism of action: how Qfitlia (fitusiran) helps restore hemostasis by lowering antithrombin for people with hemophilia. [webpage on the internet]. Morristown (NJ), Sanofi. [cited 2025 Jun 13] Available from: https://pro.campus.sanofi/us/products/qfitlia/mechanism-of-action
3. FDA. FDA. FDA approves Novel Treatment for Hemophilia A or B, With or Without Factor Inhibitors. [press release on the internet]. Available from: https://www.fda.gov/news-events/press-announcements/fda-approvesnovel-treatment-hemophilia-or-b-or-without-factor-inhibitors
4. Sanofi. Sanofi presents amended protocols in fitusiran clinical studies at EAHAD 2021. [webpage on the internet]. Morristown (NJ), Sanofi. [cited 2025 Jun 13]. Available from: https://www.sanofi.com/en/medi-room/press-releases/2021/2021-02-05-16-30-00-2170841
5. Young G, Kavakli K, Klamroth R, Matsushita T, Peyvandi F, Pipe S, et al. Safety and efficacy of a fitusiran antithrombin-based dose regimen in people with hemophilia A or B: the ATLAS-OLE study. Blood. March 7, 2025;1-23

Review History

10/8/25 – Created for P&T. Qfitlia will be managed on pharmacy and medical benefit. MB policy was created. Effective 11/17/25