POLICY Document for QFITLIA

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

CAREFIRST: EXCEPTIONS CRITERIA
HEMOPHILIA B

PREFERRED PRODUCTS: ALPROLIX, BENEFIX, IDELVION

Client Requested: The intent of the criteria is to ensure that patients follow selection elements as established by CareFirst.

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the Factor IX products specified in this policy. Coverage for targeted product is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Factor IX Products

	Product(s)
Preferred*	• **Alprolix** (coagulation factor IX [recombinant], Fc fusion protein) • **Benefix** (coagulation factor IX [recombinant]) • **Idelvion** (coagulation factor IX [recombinant], albumin fusion protein)
Targeted	• **Alhemo** (concizumab) • **AlphaNine SD** (coagulation factor IX [human])

	• **Hympavzi** (marstacimab) • **Ixinity** (coagulation factor IX [recombinant]) • **Profilnine SD** (factor IX complex) • **Qfitlia** (fitusiran) • **Rebinyn** (coagulation factor IX [recombinant], glycoPEGylated) • **Rixubis** (coagulation factor IX [recombinant])

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Coverage for a targeted product is provided when any of the following criteria is met:

A. For Hympavzi:
   a. The request is for Hemophilia A prophylaxis.

B. For Alhemo and Qfitlia, when any of the following is met:
   a. The request is for Hemophilia A prophylaxis.
   b. The request is for Hemophilia B prophylaxis in the presence of Factor IX inhibitors.

C. For all non-preferred Factor IX products:
   a. Member has a documented inadequate response, contraindication, or intolerable adverse event to all preferred products.

Member has a documented inadequate response, contraindication, or intolerable adverse event to all preferred products.

Section 2: Clinical Criteria

Specialty Guideline Management
Qfitlia

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Qfitlia	fitusiran

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Qfitlia is 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.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

For initial requests: Chart notes, lab tests documenting all of the following (where applicable):

- Severe factor VIII (factor VIII level of <1%) or IX (factor IX level of ≤ 2%) deficiency.
- Baseline antithrombin (AT) activity.
- Baseline hepatic assessments.

For continuation requests: Chart notes documenting benefit from therapy (e.g., reduced frequency or severity of bleeds).

Prescriber Specialties

The medication must be prescribed by or in consultation with a hematologist.

Coverage Criteria

Hemophilia A and Hemophilia B[1]

Authorization of 12 months may be granted for hemophilia A and hemophilia B when all of the following criteria are met:

- Member is 12 years of age or older.
- Member has severe factor VIII deficiency (defined as factor VIII level of <1%) or severe factor IX deficiency (defined as factor IX level of ≤ 2%).
- Member must be using the requested medication for routine prophylaxis to prevent or reduce the frequency of bleeding episodes.
- Member will not use the requested medication to treat breakthrough bleeding.
- Member does not have co-existing coagulation disorders (other than hemophilia A or B).

- Member does not have a history of arterial or venous thromboembolism, significant valvular disease or atrial fibrillation, or co-existing thrombophilic disorder (e.g., Factor V Leiden mutation).
- Member does not have a history of symptomatic gallbladder disease.
- Member does not have a history of or is planning to undergo immune tolerance treatment.
- Member does not have the following laboratory assessments at baseline:
  - Antithrombin (AT) activity < 60%.
  - Alanine transaminase (ALT) and/or aspartate aminotransferase (AST) greater than 1.5 times the upper limit of normal (ULN).
- Member does not have clinically significant liver disease.
- Member will not use the requested medication in combination with Alhemo, Hemlibra, or Hympavzi.
- Member has not previously received treatment with a gene therapy product (e.g., Beqvez, Hemgenix, Roctavian) for the treatment of hemophilia A or B.
- Prophylactic use of bypassing agents, factor VIII products (e.g., Advate, Adynovate, Eloctate), and factor IX products (e.g., Alprolix, Ixinity, Rebinyn) will be discontinued no later than 7 days after the initial dose of Qfitlia.
- Provider attests that AT activity and liver enzymes will be monitored per the protocol outlined in the prescribing information.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in coverage criteria section when all of the following are met:

- Member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds).
- Member is not using the requested medication in combination with bypassing agents, factor VIII products (e.g., Advate, Adynovate, Eloctate) or factor IX products (e.g., Alprolix, Ixinity, Rebinyn) for prophylactic use.

REFERENCES:

SECTION 1

1. Alhemo [package insert]. Plainsboro, NJ: Novo Nordisk Inc; July 2025.
2. AlphaNine SD [package insert]. Los Angeles, CA: Grifols Biologicals Inc; November 2022.
3. Alprolix [package insert]. Cambridge, MA: Biogen Idec Inc.; October 2020.
4. Benefix [package insert]. Philadelphia, PA: Wyeth Pharmaceutical LLC; September 2021.
5. Hympavzi [package insert]. New York, NY: Pfizer Inc; September 2025.
6. Idelvion [package insert]. Kankakee, IL: CSL Behring LLC; June 2023.
7. Ixinity [package insert]. Chicago, IL: Medexus Pharma, Inc; March 2024.
8. Profilnine SD [package insert]. Los Angeles, CA: Grifols Biologicals Inc; August 2010.
9. Qfitlia [package insert]. Cambridge, MA: Genzyme Corporation; September 2025.
10. Rebinyn [package insert]. DK-2880 Bagsvaerd, Denmark: Novo Nordisk A/S; August 2022
11. Rixubis [package insert]. Lexington, MA. Baxalta US Inc.; June 2020

SECTION 2

1. Qfitlia [package insert]. Cambridge, MA: Genzyme Corporation; September 2025.