

Qfitlia (fitusiran)
Effective 10/01/2025

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| Plan | <input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange | Program Type | <input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy |
| Benefit | <input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit | | |
| Specialty Limitations | This medication has been designated specialty and must be filled at a contracted specialty pharmacy. | | |
| Contact Information | Medical Benefit Pharmacy Benefit | Phone: 833-895-2611 Phone: 800-711-4555 | Fax: 888-656-6671 Fax: 844-403-1029 |
| Exceptions | N/A | | |

Overview

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.

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted when all of the following criteria are met:

- Member has one of the following diagnoses:
 - Hemophilia A with or without factor VIII inhibitors
 - Hemophilia B with or without factor IX inhibitors
- Member is 12 years of age or older
- Requested medication will be used for prophylaxis to prevent or reduce the frequency of bleeding episodes
- Member has the presence of antithrombin (AT) activity greater than 60%
- Requested medication is prescribed by or in consultation with a hematologist
- Member will discontinue use of other prophylactic Factor VIII or factor IX therapies after the first week of treatment with Qfitlia

Continuation of Therapy

Requests for reauthorization will be approved when the following criteria are met:

- Requested medication continues to be used for prophylaxis to prevent or reduce the frequency of bleeding episodes.
- Member demonstrates a positive clinical response to therapy (e.g., reduced frequency or severity of bleeds)
- Member is not using the requested medication in combination with prophylactic Factor VIII or Factor IX therapies

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.

References

1. Kenet G, Nolan B, Zulfikar B, et al. Fitusiran prophylaxis in people with hemophilia A or B who switched from prior BPA/CFC prophylaxis: the ATLAS-PPX trial. *Blood*. 2024;143(22):2256-2269. doi:10.1182/blood.2023021864.
2. Manco-Johnson MJ, Lundin B, Funk S, et al. Effect of late prophylaxis in hemophilia on joint status: a randomized trial. *J Thromb Haemost*. 2017;15(11):2115-2124. doi:10.1111/jth.13811.
3. Manco-Johnson MJ, Kempton CL, Reding MT, et al. Randomized, controlled, parallel-group trial of routine prophylaxis vs. on-demand treatment with sucrose-formulated recombinant factor VIII in adults with severe hemophilia A (SPINART) [published correction appears in *J Thromb Haemost*. 2014;12(1):119-22]. *J Thromb Haemost*. 2013;11(6):1119-1127. doi:10.1111/jth.12202.
4. National Bleeding Disorders Foundation (NBDF; formerly the National Hemophilia Foundation [NHF]). MASAC recommendation concerning prophylaxis for hemophilia A and B with and without inhibitors. MASAC Document #267. April 2022a. Accessed April 23, 2025. <https://www.bleeding.org/healthcare-professionals/guidelines-on-care/masac-documents/masac-document-267-masac-recommendation-concerning-prophylaxis-for-hemophilia-a-and-b-with-and-without-inhibitors>
5. National Bleeding Disorders Foundation (NBDF; formerly National Hemophilia Foundation [NHF]). MASAC recommendation on SIPPET (Survey of Inhibitors in Plasma-Product-Exposed Toddlers): Results and recommendations for treatment products for previously untreated patients with hemophilia A. MASAC Document #243. June 28, 2016. Accessed April 23, 2025. <https://www.bleeding.org/sites/default/files/document/files/243sippet.pdf>
6. National Bleeding Disorders Foundation (NBDF; formerly the National Hemophilia Foundation [NHF]). MASAC recommendation regarding the use of recombinant clotting factor products with respect to pathogen transmission. MASAC Document #226. May 2014. Accessed April 23, 2025. <https://www.bleeding.org/healthcare-professionals/guidelines-on-care/masac-documents/masac-document-226-recommendation-regarding-the-use-of-recombinant-clotting-factor-products-with-respect-to-pathogen-transmission>
7. National Bleeding Disorders Foundation (NBDF; formerly National Hemophilia Foundation [NHF]). MASAC recommendations concerning products licensed for the treatment of hemophilia and selected disorders of the coagulation system. MASAC Document #290. October 2024. Accessed April 23, 2025. <https://www.bleeding.org/healthcare-professionals/guidelines-on-care/masac-documents/masac-document-290-masac-recommendations-concerning-products-licensed-for-the-treatment-of-hemophilia-and-selected-disorders-of-the-coagulation-system>
8. Qfitlia (fitusiran) [prescribing information]. Cambridge, MA: Genzyme Corporation; March 2025.
9. Rota M, Cortesi PA, Steinitz-Trost KN, Reininger AJ, Gringeri A, Mantovani LG. Meta-analysis on incidence of inhibitors in patients with haemophilia A treated with recombinant factor VIII products. *Blood Coagul Fibrinolysis*. 2017;28(8):627-637. doi:10.1097/MBC.0000000000000647.
10. 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.
11. World Federation of Hemophilia (WFH). Annual global survey 2023. October 2024. WFH Web site. Accessed April 23, 2025. <https://www1.wfh.org/publications/files/pdf-2525.pdf>



12. World Federation of Hemophilia (WFH). Guidelines of the management of hemophilia. 3rd ed. 2020. WFH Web site. Accessed April 23, 2025. [Education and eLearning – WFH - World Federation of Hemophilia](#).
13. Young G, Kavakli K, Klamroth R, et al. Safety and efficacy of a fitusiran antithrombin-based dose regimen in people with hemophilia A or B: the ATLAS-OLE study. *Blood*. Published online March 7, 2025. doi:10.1182/blood.2024027008.
14. 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.

Review History

07/09/2025 – Created and reviewed at July P&T. Effective 10/01/2025.

