

Hypnavzi (marstacimab-hncq)
Effective 07/01/2025

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Contact Information	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview

Hypnavzi (marstacimab-hncq) 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 inhibitor, or
- Hemophilia B (congenital factor IX deficiency) without factor 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 the following criteria are met:

- Member has one of the following diagnoses:
 - Hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors
 - Hemophilia B (congenital factor IX deficiency) without factor IX inhibitors
- Requested medication is being used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
- Member is 12 years of age or older
- Requested medication is prescribed by or in consultation with a hematologist
- Requests for Hemophilia A:** Member meets ALL of the following:
 - Member has severe Hemophilia A (FVIII activity < 1)
 - Member will discontinue use of other prophylactic therapies (e.g., Advate, Adynovate, Eloctate, etc)
- Requests for Hemophilia B:** Member meets ALL of the following:
 - Member has moderately severe to severe Hemophilia B (FIX activity ≤ 2)
 - Member will discontinue use of other prophylactic therapies (e.g., Alprolix, BeneFIX, Idelvion, Rebinyn, etc)

Continuation of Therapy

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

1. Member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds)
2. Member is not using the requested medication in combination with prophylactic Factor VIII products for hemophilia A or prophylactic Factor IX products for hemophilia B

Limitations

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

References

1. Hymapavzi (marstacimab-hcnq) [prescribing information]. New York, NY: Pfizer Inc.; October 2024.
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. Matino D, Gould T, Teeter J, et al. Descriptive characterization of bleeding events in participants with severe hemophilia A or B without inhibitors, receiving prophylactic marstacimab treatment. Oral and Poster presentation at: The American Society of Hematology (ASH) Annual Meeting & Exposition; December 7-10, 2024: San Diego, CA.
5. National Bleeding Disorders Foundation (NBDF; formerly the National Hemophilia Foundation [NHF]). Bleeding disorders A-Z: Types. NBDF Web site. 2024. Accessed December 19, 2024. <https://www.hemophilia.org/Bleeding-Disorders/Types-of-Bleeding-Disorders>
6. 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.
7. World Federation of Hemophilia (WFH). Annual global survey 2023. October 2024. Accessed December 20, 2024. <https://www1.wfh.org/publications/files/pdf-2525.pdf>
8. World Federation of Hemophilia (WFH). Guidelines of the management of hemophilia. 3rd ed. 2020. WFH Web site. Accessed December 19, 2024. [Education and eLearning – WFH - World Federation of Hemophilia](#).

Review History

04/09/2025 – Reviewed at April P&T. Effective 07/01/2025.

