Neighborhood Health Plan OF RHODE ISLAND™
910 Douglas Pike, Smithfield, RI 02917 : 1-800-963-1001 : nhpri.org

Hympavzi ® (marstacimab-hncq)
(Subcutaneous)

Effective Date: 05/01/2025
Reviewed Date: 02/10/2025, 9/17/2025
Pharmacy Scope: Medicaid
Medical Scope: Medicaid, Commercial, Medicare

I. Length of Authorization

Coverage will be provided for 6 months and may be renewed

II. Dosing Limits

A. Quantity Limit (max daily dose)

- Hympavzi 150mg/ml: 4 syringes/pens (4 ml) per 28 days
- Quantity limit exception for first fill of 5 ml per 28 days (0.179ml/day) to be provided to allow for initial loading dose of 300mg (2 ml), followed one week later by 150mg weekly
- Quantity limit exception for 300mg weekly (8 ml per 28 days or 0.286 ml per day) as maintenance dose may be provided with documentation of inadequate clinical response (i.e. control of bleeding events) at lower dose in patients weighing greater than or equal to 50 kg
- Max weekly dose is 300mg weekly

B. Max Units (per dose and over time) [HCPCS Unit]:

– 300 mg or 600 units every week

III. Summary of Evidence

Hympavzi (marstacimab-hncq) is 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 without factor VIII inhibitors or hemophilia B without factor IX inhibitors (neutralizing antibodies). Hemophilia A and hemophilia B are genetic bleeding disorders caused by a dysfunction or deficiency of coagulation factor VIII (FVIII) or IX (FIX), respectively. Hympavzi's approval is based on the Phase 3 BASIS study which was an open-label, multi-center study in 116 adult and pediatric male patients with either severe hemophilia A or severe hemophilia B, both without inhibitors. For the first six months of this study, patients received treatment with replacement factor either on-demand (33 patients) or prophylactically (83 patients). These patients then received Hympavzi prophylaxis for 12 months. The primary measure of efficacy of Hympavzi was the annualized bleeding rates of treated bleeds. In the patients receiving on-demand factor replacement during the first six months of the study, the estimated annualized bleeding rate was 38 compared to the estimated annualized bleeding rate during treatment with Hympavzi of 3.2, showing that Hympavzi

was superior to on-demand factor replacement. In the initial six-month period during which patients received prophylactic factor replacement, the estimated annualized bleeding rate was 7.85 and was 5.08 during the subsequent 12 months on Hympavzi prophylaxis, showing that Hympavzi provided similar bleeding rates. The most common side effects of Hympavzi are injection site reactions, headache and pruritis.

IV. Initial Approval Criteria [1-3,8,10-11]

Coverage is provided in the following conditions:

- Member is at least 12 years of age; **AND**
- Hympavzi must be prescribed by, or consultation with a hematologist; **AND**
- Member will initiate maintenance therapy at the lower range of dosing (i.e., 150 mg every week); **AND**
- Will not be used for the treatment of breakthrough bleeds *(Note: Factor VIII or Factor IX products may be administered on an as needed basis for the treatment of breakthrough bleeds in members being treated with Hympavzi(marstacimab)*; **AND**
- Female members of reproductive potential are not pregnant prior to initiating therapy with Hympavzi (marstacimab); **AND**
- Member does not have a history of coronary artery disease, venous or arterial thrombosis or ischemic disease.
- Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

Universal Criteria

- Will not be used in combination with clotting factor products (i.e., factor VIII or factor IX concentrates), Qfiltia or Hemlibra as <u>prophylactic</u> therapy – *Therapy can be initiated at any time after discontinuing clotting factor concentrates (Note: factor VIII or factor IX products can be administered for the treatment of breakthrough bleeds while receiving marstacimab)*** *See chart below*; **AND**
- Member has not previously received treatment with a gene therapy product (e.g., Roctavian) for the treatment of hemophilia A or a gene therapy product (e.g., Hemgenix) for the treatment of hemophilia B

Hemophilia A (congenital factor VIII deficiency) without inhibitors † Φ

- Diagnosis of congenital factor VIII deficiency without inhibitors has been confirmed by blood coagulation testing; **AND**
- Must be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
- Member meets ONE of the following:
    - Has had an inadequate response, intolerance, or contraindication to compliant use of a factor VIII product (e.g., Advate, Koate/Koate DVI, Hemofil, etc.) and Hemlibra; **OR**
    - Has had at least 6 acute bleeding episodes in the previous 6 months.
- Used as treatment in one of the following:
    - Primary prophylaxis in members with severe factor VIII deficiency (factor VIII level of <1%); **OR**
    - Secondary prophylaxis in members with at least <u>TWO</u> documented episodes of spontaneous bleeding into joints;

Hemophilia B (congenital factor IX deficiency aka Christmas Disease) without inhibitors † Φ

- Diagnosis of congenital factor IX deficiency without inhibitors has been confirmed by blood coagulation testing; **AND**
- Must be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
- Member meets ONE of the following:
    - Has had an inadequate response, intolerance, or contraindication to compliant use of a factor IX product (e.g., Benefix, Rixubis, Alphanine, etc.); **OR**
    - Has had at least 6 acute bleeding episodes in the previous 6 months.
- Used as treatment in one of the following:
    - Primary prophylaxis in members with severe factor IX deficiency (factor IX level of <1%); **OR**
    - Secondary prophylaxis in members with at least TWO documented episodes of spontaneous bleeding into joints;

† FDA Approved Indication(s); **‡** Compendia Recommended Indication(s); **Φ** Orphan Drug

*****Drugs for Hemophilia A & B**

Hemophilia A & B Drug Chart	
Factor VIIa (Hemophilia A or B)	
Novoseven RT	J7189
Sevenfact	J7212
Anti-Inhibitor Coagulant Complex (Hemophilia A or B)	
Feiba	J7198
Factor VIII (Hemophilia A)	
Advate	J7192
Kogenate FS	J7192
Helixate FS	J7192
Recombinate	J7192
Kovaltry	J7211
Eloctate	J7205
Koate / Koate-DVI	J7190
Hemofil M	J7190
Novoeight	J7182

Nuwiq	J7209
Obizur	J7188
Xyntha / Xyntha Solofuse	J7185
Afstyla	J7210
Adynovate	J7207
Jivi	J7208
Esperoct	J7204
Altuviiio	J7214
Factor IX (Hemophilia B)	
AlphaNine SD	J7193
Mononine	J7193
Alprolix	J7201
Profilnine	J7194
BeneFIX	J7194
Ixinity	J7213
Rixubis	J7200
Idelvion	J7202
Rebinyn	J7203

V. Dispensing Requirements for Rendering Providers (Hemophilia Management Program)

- Prescriptions cannot be filled without an expressed need from the member, caregiver or prescribing practitioner. Auto-filling is not allowed.
- Monthly, rendering provider must submit for authorization of dispensing quantity before delivering factor product.
- The cumulative amount of medication(s) the member has on-hand should be taken into account when dispensing factor product.
- Dispensing requirements for renderings providers are a part of the hemophilia management program. This information is not meant to replace clinical decision making when initiating or modifying medication therapy and should only be used as a guide

VI. Renewal Criteria [1-3,8]

Coverage can be renewed based upon the following criteria:

- Member continues to meet the indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section IV; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: thromboembolic events, hypersensitivity, etc.; **AND**
    - Member has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline); **OR**
    - Member requires a dose escalation* (up to the maximum dose and frequency specified below) provided that the member meets all the following criteria:
        - Member weighs greater than or equal to 50 kg
        - Control of bleeding events has been inadequate (i.e., member has experienced two or more breakthrough bleeds while on maintenance therapy at the lower dose)
        - Member has been fully adherent to maintenance therapy for at least six months at the lower dose

**Note: Safety and efficacy of Hympavzi at doses above 300 mg weekly has not been established.*

VII. Dosage/Administration [1]

Indication	Dose
Routine Prophylaxis in Congenital Hemophilia A or Hemophilia B without inhibitors	**Loading Dose:** • 300 mg (two 150 mg subcutaneous injections) **Maintenance Dose:** • One week after the loading dose, initiate maintenance dosing of 150 mg every week by subcutaneous injection on the same day each week, at any time of day. • Consider a dose adjustment to 300 mg subcutaneous injection weekly in members weighing greater than or equal to 50 kg when control of bleeding events is judged to be inadequate by the healthcare provider. Safety and efficacy of Hympavzi at doses above 300 mg weekly have not been established. *If more than one injection is required to deliver a complete dose, administer each injection at a different injection site.*

Indication	Dose
• Hympavzi is intended for use under the guidance of a healthcare provider. After proper training in subcutaneous injection technique, a member may self-inject or the member's caregiver may administer it, if a healthcare provider determines that it is appropriate.	

VIII. Billing Code/Availability Information

HCPCS Code:

- J7172 – Hympavzi

NDC:

- Hympavzi single-dose prefilled syringe: 00069-1510-xx
- Hympavzi single-dose prefilled pen: 00069-2151-xx

IX. References

1. Hympavzi [package insert]. New York, NY; Pfizer, Inc. February 2025. Accessed July 2025.
2. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. Revised April 11, 2024. National Hemophilia Foundation. MASAC Document #284; April 2024. Available at: https://www.bleeding.org. Accessed May 2024.
3. Guidelines for the Management of Hemophilia. 3rd Edition. World Federation of Hemophilia 2020. Available at: https://www1.wfh.org/publications/files/pdf-1863.pdf. Accessed May 2024.
4. Annual Review of Factor Replacement Products. Oklahoma Health Care Authority Review Board. Updated Dec 2020. Accessed May 2024.
5. Graham A1, Jaworski K. Pharmacokinetic analysis of anti-hemophilic factor in the obese patient. Haemophilia. 2014 Mar;20(2):226-9.
6. Croteau SE1, Neufeld EJ. Transition considerations for extended half-life factor products. Haemophilia. 2015 May;21(3):285-8.
7. Mingot-Castellano, et al. Application of Pharmacokinetics Programs in Optimization of Haemostatic Treatment in Severe Hemophilia a Patients: Changes in Consumption, Clinical Outcomes and Quality of Life. Blood. 2014 December; 124 (21).
8. MASAC Recommendation Concerning Prophylaxis for Hemophilia A and B with and without Inhibitors. Revised April 27, 2022. National Hemophilia Foundation. MASAC Document #267; April 2022. Available at: https://www.bleeding.org. Accessed May 2024.
9. UKHCDO protocol for first line immune tolerance induction for children with severe haemophilia A: A protocol from the UKHCDO Inhibitor and Paediatric Working Parties. 2017. Available at: http://www.ukhcdo.org/guidelines. Accessed May 2024.
10. Hoots, WK. (2024). Hemophilia A and B: Routine management including prophylaxis. In Leung LLK, Tirnauer JS (Eds.), *UptoDate*. Last updated: April 16, 2024. Accessed May 13, 2024. Available from https://www.uptodate.com/contents/hemophilia-a-and-b-routine-management-including-prophylaxis?search=hemophilia%20a&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2#H978189854.
11. Matino D, Acharya S, Palladino A, et al. Efficacy and Safety of the Anti-Tissue Factor Pathway Inhibitor Marstacimab in Participants with Severe Hemophilia without Inhibitors: Results from the Phase 3 Basis Trial.

Blood, Volume 142, Supplement 1, 2023, Page 285, ISSN 0006-4971, https://doi.org/10.1182/blood-2023-181263.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D66	Hereditary factor VIII deficiency
D67	Hereditary factor IX deficiency

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Policy Rationale: Hympavzi was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Hympavzi to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.