MEDICAL MUTUAL®

Drug Policy

Policy:	**250202**	**Initial Effective Date: 12/31/2024**
Code(s):	**HCPCS J3590**	**Annual Review Date: 06/19/2025**
SUBJECT:	**Hympavzi ® (marstacimab-hncq)**	**Last Revised Date: 06/19/2025**

Subject to: ☐Site of Care
☐Medication Sourcing

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

I. Length of Authorization

Coverage will be provided for 6 months and may be renewed every 12 months thereafter.

II. Dosing Limits

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

- 600 billable units every week

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

Submission of supporting clinical documentation (including but not limited to medical records, chart notes, lab results, and confirmatory diagnostics) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission as part of the evaluation of this request. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e., genetic, and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax. Failure to submit the medical records may result in the denial of the request due to inability to establish medical necessity in accordance with policy guidelines.

Coverage is provided in the following conditions:

- Patient is at least 12 years of age; **AND**
- Patient 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 patients being treated with marstacimab)*; **AND**

- Female patients of reproductive potential are not pregnant prior to initiating therapy with marstacimab; **AND**

Universal Criteria

- Will not be used in combination with another agent used as prophylactic therapy for Hemophilia A or B; **AND**

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

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- Must be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
- Used as treatment in one of the following:
    - Primary prophylaxis in patients with severe factor VIII deficiency (factor VIII level of <1%); **OR**
    - Secondary prophylaxis in patients with at least TWO documented episodes of spontaneous bleeding into joints; **AND**
- Patient has tried and had an inadequate response to emicizumab AND an antihemophilic Factor VIII agent, that are used for prophylaxis, unless contraindicated or not tolerated

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

- Diagnosis of congenital factor IX deficiency has been confirmed by blood coagulation testing; **AND**
- Must be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
- Used as treatment in one of the following:
    - Primary prophylaxis in patients with severe factor IX deficiency (factor IX level of <1%); **OR**
    - Secondary prophylaxis in patients with at least TWO documented episodes of spontaneous bleeding into joints; **AND**
- Patient has tried and had an inadequate response to an antihemophilic Factor IX agent used for prophylaxis, unless contraindicated or not tolerated

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

IV. Renewal Criteria [1-3,8]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: thromboembolic events, hypersensitivity, etc.; **AND**
    - Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline); **OR**
    - Patient requires a dose escalation* (up to the maximum dose and frequency specified below) and meets all the following criteria:
        - Patient weighs greater than or equal to 50 kg
        - Control of bleeding events has been inadequate (i.e., patient has experienced two or more breakthrough bleeds while on maintenance therapy at the lower dose)
        - Patient has been fully adherent to maintenance therapy for at least six months at the lower dose

V. 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. *** Dose Escalation During Treatment:** • Consider a dose adjustment to 300 mg subcutaneous injection weekly in patients 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 at doses above 300 mg weekly have not been established.
• Marstacimab is intended for use under the guidance of a healthcare provider. After proper training in subcutaneous injection technique, a patient may self-inject or the patient's caregiver may administer it, if a healthcare provider determines that it is appropriate. • If more than one injection is required to deliver a complete dose, administer each injection at a different injection site.	

VI. Billing Code/Availability Information

HCPCS Code(s):

- C9304 – Injection, marstacimab-hncq, 0.5 mg; 1 billable unit = 0.5 mg *(Discontinue use on 07/01/2025)*

- J3590 – Unclassified biologic *(Discontinue use on 07/01/2025)*
- J7172 – Injection, marstacimab-hncq, 0.5 mg; 1 billable unit = 0.5 mg *(Effective 07/01/2025)*

NDC(s):

- Hympavzi 150 mg/mL single-dose prefilled syringe: 00069-1510-xx
- Hympavzi 150 mg/mL single-dose prefilled pen: 00069-2151-xx

VII. References

1. Hympavzi [package insert]. New York, NY; Pfizer, Inc. October 2024. Accessed April 2025.
2. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. Revised October 2, 2024. National Hemophilia Foundation. MASAC Document #290. Available at: https://www.bleeding.org. Accessed May 2025.
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.
4. Annual Review of Factor Replacement Products. Oklahoma Health Care Authority Review Board. Updated Dec 2020.
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; Available at: https://www.bleeding.org. Accessed May 2025.
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.
10. Malek N. (2025). Hemophilia A and B: Routine management including prophylaxis. In Shapiro AD, Tirnauer JS (Eds.), *UptoDate*. Last updated: April 29, 2025. Accessed May 6, 2025. Available from https://www.uptodate.com/contents/hemophilia-a-and-b-routine-management-including-prophylaxis
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.

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Appendix 1 – 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 Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

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,	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	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not

medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

HCPCS Code(s):	
J3590	Unclassified biologics