

Clinical Policy: Marstacimab-hncq (Hypavzi)

Reference Number: CP.PHAR.674

Effective Date: 10.11.24

Last Review Date: 02.26

Line of Business: Commercial, HIM/ICHRA, Medicaid

[Coding Implications](#)[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Marstacimab-hncq (Hypavzi[™]) is a tissue factor pathway inhibitor (TFPI) antagonist.

FDA Approved Indication(s)

Hypavzi is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 6 years of age and older with:

- hemophilia A (congenital factor VIII [FVIII] deficiency) with or without FVIII inhibitors, or
- hemophilia B (congenital factor IX [FIX] deficiency) with or without FIX inhibitors.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that Hypavzi is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria**A. Congenital Hemophilia A or B (must meet all):**

1. Prescribed for routine prophylaxis of bleeding episodes in members with one of the following (a or b):
 - a. Congenital hemophilia A (FVIII deficiency);
 - b. Congenital hemophilia B (FIX deficiency);
2. Prescribed by or in consultation with a hematologist;
3. Age $\geq$ 6 years;
4. For members who are new to Hypavzi therapy and have not previously used bypassing agents, FVIII, or FIX products for routine prophylaxis: Member meets one of the following (a, b, or c):
 - a. For hemophilia A: Member has severe hemophilia, defined as FVIII level of $< 1\%$;
 - b. For hemophilia B: Member has moderately severe to severe hemophilia, defined as FIX level of $\leq 2\%$;
 - c. Member has experienced at least one serious spontaneous bleed (*see Appendix D*);
5. One of the following (a, b or c; *see Appendix D*):[^]

^For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395

 - a. Member had ≥ 6 acute bleeding episodes in the previous 6 months treated with a bypassing agent, FVIII product, or FIX product;
 - b. For hemophilia A, both (i and ii):

- i. Failure of a bypassing agent or FVIII product used for routine prophylaxis as assessed and documented by prescriber, unless clinically significant adverse effects are experienced or all are contraindicated;*
 - ii. Failure of Hemlibra[®] as assessed and documented by prescriber, unless contraindicated or clinically significant adverse effects are experienced;*
 - c. For hemophilia B: Failure of a bypassing agent or FIX product used for routine prophylaxis as assessed and documented by prescriber, unless clinically significant adverse effects are experienced or all are contraindicated;*
- *Prior authorization may be required for bypassing agents, FVIII products, FIX products, and Hemlibra*
- 6. Hympavzi is not prescribed concurrently with another hemophilia prophylaxis agent (e.g., Alhemo[®], Hemlibra[®], Qfitlia[®], bypassing agents, FVIII or FIX products as prophylactic therapy*);
**On-demand usage of a bypassing agent, FVIII product, or FIX product may be continued*
 - 7. Dose does not exceed one of the following (a or b):
 - a. For age ≥ 12 years, both of the following (i and ii):
 - i. Loading (one-time) dose (both 1 and 2):
 - 1) 300 mg;
 - 2) 2 pens or syringes;
 - ii. Maintenance dose (both 1 and 2):
 - 1) 150 mg per week;
 - 2) 1 pen or syringe per week;
 - b. For age 6 years to < 12 years, both of the following (i and ii):
 - i. Loading (one-time) dose (both 1 and 2):
 - 1) 150 mg;
 - 2) 1 pen or syringe;
 - ii. Maintenance dose (both 1 and 2):
 - 1) 75 mg per week;
 - 2) 1 pen or syringe per week.

Approval duration:

Medicaid/HIM/ICHRA – 12 months

Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2):

- 1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
- 2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND

criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Congenital Hemophilia A or B (must meet all):

1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy (e.g., reduction in the number of all bleeds, joint bleeds, and/or target joint bleeds over time);
3. Hympavzi is not prescribed concurrently with another hemophilia prophylaxis agent (e.g., Alhemo, Hemlibra, Qfitlia, bypassing agents, FVIII or FIX products as prophylactic therapy*);
**On-demand usage of a bypassing agent, FVIII product, or FIX product may be continued*
4. If request is for a dose increase, new maintenance dose does not exceed one of the following (a or b):
 - a. For age ≥ 12 years, one of the following (i or ii):
 - i. Both of the following (1 and 2):
 - 1) 150 mg per week;
 - 2) 1 pen or syringe per week;
 - ii. All of the following (1, 2, 3, and 4):
 - 1) 300 mg per week;
 - 2) 2 pens or syringes per week;
 - 3) Member's weight ≥ 50 kg;
 - 4) Control of bleeding events on a maintenance dose of 150 mg per week is judged to be inadequate by the provider;
 - b. For age 6 years to < 12 years, one of the following (i or ii):
 - i. Both of the following (1 and 2):
 - 1) 75 mg per week;
 - 2) 1 pen or syringe per week;
 - ii. All of the following (1, 2, 3, and 4):
 - 1) 150 mg per week;
 - 2) 1 pen or syringe per week;
 - 3) Member's weight ≥ 25 kg;
 - 4) Control of bleeding events on a maintenance dose of 75 mg per week is judged to be inadequate by the provider.

Approval duration:

Medicaid/HIM/ICHRA – 12 months

Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

FIX: factor IX

FVIII: factor VIII

TFPI: tissue factor pathway inhibitor

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen
<i>Non-factor product for routine prophylaxis in hemophilia A</i>	
Hemlibra [®] (emicizumab-kxwh)	Loading dose of 3 mg/kg SC weekly for four weeks, followed by a maintenance dose of 1.5 mg/kg SC weekly or 3 mg/kg once every two weeks or 6 mg/kg once every four weeks
<i>FVIII products for control and prevention of bleeding episodes and/or routine prophylaxis in hemophilia A - examples</i>	
Advate [®] , Adynovate [®] , Afstyl [®] , Altuviiio [®] , Elocate [®] , Esperoct [®] , Hemofil M [®] , Jivi [®] , Koate-DVI [®] , Kogenate FS [®] , Kovaltry [®] ,	See individual Prescribing Information for dosing regimen

Drug Name	Dosing Regimen
Novoeight [®] , Nuwiq [®] , Recombinate [®] , Xyntha [®]	
<i>FIX products for control and prevention of bleeding episodes and/or routine prophylaxis in hemophilia B - examples</i>	
AlphaNine [®] SD, Alprolix [®] , BeneFIX [®] , Idelvion [®] , Ixinity [®] , Rebinyon [®] , Rixubis [®]	See individual Prescribing Information for dosing regimen
<i>Bypassing products for control and prevention of bleeding episodes and/or for routine prophylaxis - examples</i>	
NovoSeven [®] RT, SevenFact [®] , Feiba [®]	See individual Prescribing Information for dosing regimen

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: General Information

- There are no strict criteria for failing a bypassing agent, factor product, or Hemlibra for routine prophylaxis; however, the following reasons are acceptable to fulfill the criteria:
 - Prescriber has documented clinical criteria which support his or her assessment that the member has failed a bypassing agent, factor product, or Hemlibra therapy.
 - Clinically significant bleeding, hemarthroses, life-threatening bleeding episodes, joint swelling, upcoming surgery/procedure not responding to current therapy, or other clinical assessment as determined by prescriber.
- Serious bleeding episodes include bleeds in the following sites: intracranial; neck/throat; gastrointestinal; joints (hemarthrosis); muscles (especially deep compartments such as the iliopsoas, calf, forearm); or mucous membranes of the mouth, nose, and genitourinary tract.
- A spontaneous bleed is defined as a bleeding episode that occurs without apparent cause and is not the result of trauma.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Routine prophylaxis of bleeding episodes in hemophilia A or B with or without inhibitors	<u>Adults and pediatric patients aged ≥ 12 years:</u> One loading dose of 300 mg SC, followed by a maintenance dose of 150 mg SC once weekly on the same day each week, at any time of day. Consider a dose adjustment to 300 mg SC injection weekly in patients weighing ≥ 50 kg when control of bleeding events is judged to be inadequate by the healthcare provider.	• Adults and pediatric patients aged ≥ 12 years: 300 mg/week • Pediatric patients aged 6 years to < 12 years: 150 mg/week

Indication	Dosing Regimen	Maximum Dose
	<u>Pediatric patients aged 6 years to < 12 years:</u> One loading dose of 150 mg SC, followed by a maintenance dose of 75 mg SC once weekly on the same day each week, at any time of day. Consider a dose adjustment to 150 mg SC injection weekly in patients weighing ≥ 25 kg when control of bleeding events is judged to be inadequate by the healthcare provider.	

VI. Product Availability

- Single-dose prefilled pens: 150 mg/mL, 75 mg/0.5 mL
- Single-dose prefilled syringes: 150 mg/mL, 75 mg/0.5 mL

VII. References

1. Hymovavzi Prescribing Information. New York, NY: Pfizer; June 2026. Available at: <https://www.hymovavzi.com/>. Accessed June 22, 2026.
2. Matino D, Palladino A, Taylor CT, et al. Marstacimab prophylaxis in hemophilia A/B without inhibitors: results from the phase 3 BASIS trial. *Blood*. 2025;146(14):1654-1663.
3. Matino D, Acharya SS, Taylor CT, et al. Efficacy and safety of marstacimab prophylaxis in hemophilia A/B with inhibitors: results from the phase 3 BASIS trial. *Blood*. 2026;147(9):920-931.
4. Srivastava A, Santagostino E, Dougall A, et al. WFH guidelines for the management of hemophilia. *Haemophilia*. 2020;26(suppl 6):1-158.
5. Medical and Scientific Advisory Council (MASAC) of the National Bleeding Disorders Foundation (formerly National Hemophilia Foundation): Database of treatment guidelines. Available at: <https://www.hemophilia.org/healthcare-professionals/guidelines-on-care/masac-documents>. Accessed June 22, 2026.
6. Rezende SM, Neumann I, Angchaisuksiri P, et al. International Society on Thrombosis and Haemostasis clinical practice guideline for treatment of congenital hemophilia A and B based on the Grading of Recommendations Assessment, Development, and Evaluation methodology. *J Thromb Haemost*. 2024;22(9):2629-2652.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPSC Codes	Description
J7172	Injection, marstacimab-hncq, 0.5 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively	02.13.24	05.24
Drug is now FDA approved – criteria updated per FDA labeling: removed requirement for weight ≥ 35 kg; clarified hemophilia B from “moderate” to “moderately severe”; added option of at least one serious spontaneous bleed to the classification criteria of hemophilia A and B; removed option for ≥ 6 acute bleeding episodes in the previous 6 months; added redirection to Hemlibra for hemophilia A per SDC recommendation; added standard adverse effect or contraindication template language to failure of a FVIII or FIX product criterion; for continued therapy, added maximum maintenance dosing option of 300 mg weekly for patients weighing ≥ 50 kg when control of bleeding events is judged to be inadequate by the provider; added Commercial approval duration of 6 months or to the member’s renewal date, whichever is longer to both initial and continued therapy criteria; revised continued approval duration for Medicaid & HIM to 12 months; references reviewed and updated.	10.24.24	02.25
HCPCS code added [C9304], removed codes [C9399, J3590].	04.02.25	
HCPCS code added [J7172] replacing code [C9304].	05.16.25	
1Q 2026 annual review: added clarification that requirement for hemophilia severity associated with factor level is taken at baseline prior to use of factor products for routine prophylaxis; revised provider confirmation of discontinuation of factor products as prophylaxis to exclusion for concurrent use of hemophilia prophylaxis agent with more examples; added step therapy bypass for IL HIM per IL HB 5395; revised initial approval duration from 6 months to 12 months; references reviewed and updated.	10.23.25	02.26
RT4: added the indications of hemophilia A and B with inhibitors, updated indication to include pediatric patients 6-11 years of age, and added new 75 mg/0.5 mL strengths of prefilled dose and pen; added bypassing agent prophylaxis option to hemophilia severity requirement for members who are new to Hymovon; added option to bypass failure of prophylaxis agents with ≥ 6 acute bleeding episodes in the previous 6 months treated with a bypassing agent, FVIII, or FIX product; added option of failure with bypassing agent prophylaxis in addition to either a FVIII or FIX product; removed requirement for no documented history of inhibitors; added ICHRA line of business.	06.22.26	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program

approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

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This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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