

DRUG POLICY

Hympavzi® (marstacimab-hncq)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Hympavzi 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 (congenital factor VIII deficiency) without factor VIII inhibitors, or
- Hemophilia B (congenital factor IX deficiency) without factor IX inhibitors

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. For initial requests:
 - A. Chart notes
 - B. Lab tests documenting all of the following (where applicable):
 - i. Hemophilia A (congenital factor VIII deficiency):
 1. Severe factor VIII deficiency (factor VIII level of <1%)
 2. Absence of factor VIII inhibitors (lab test results required)
 - ii. Hemophilia B (congenital factor IX deficiency):
 1. Moderately severe to severe factor IX deficiency (factor IX level of ≤ 2%)
 2. Absence of Factor IX inhibitors (lab test results required)
2. For continuation requests:

- A. Chart notes documenting benefit from therapy (e.g., reduced frequency or severity of bleeds).

Prescriber Specialties

The requested medication must be prescribed by or in consultation with one of the following:

1. Hematologist

Criteria for Initial Approval

Hemophilia A (congenital factor VIII deficiency)

Authorization of 12 months may be granted for hemophilia A (congenital factor VIII deficiency) when all of the following criteria are met:

1. Member is 12 years of age or older
2. Member is ≥ 35 kg
3. Member has severe factor VIII deficiency (defined as factor VIII level of $<1\%$)
4. Member has no detectable or documented history of factor VIII inhibitors
5. Member must be using the requested medication for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
6. Member will not use the requested medication to treat breakthrough bleeding
7. Member meets one of the following:
 - A. Has had an inadequate response, intolerance, or contraindication to compliant use of a factor VIII product (e.g., Advate, Adynovate, Eloctate)
 - B. Has had at least 6 acute bleeding episodes in the previous 6 months
8. Member does not have a history of coronary artery disease, venous or arterial thrombosis or ischemic disease
9. Member does not have unstable or abnormal hepatic, biliary, or renal function/disease
10. Member will not use the requested medication in combination with Alhemo, Hemlibra, or Qfitlia
11. Member has not previously received treatment with a gene therapy product (e.g., Roctavian) for the treatment of hemophilia A
12. Prophylactic use of factor VIII products will be discontinued prior to starting therapy with the requested medication

Hemophilia B (congenital factor IX deficiency)

Authorization of 12 months may be granted for hemophilia B (congenital factor IX deficiency) when all of the following criteria are met:

1. Member is 12 years of age or older
2. Member is ≥ 35 kg
3. Member has moderately severe to severe factor IX deficiency (defined as factor IX level of $\leq 2\%$)
4. Member has no detectable or documented history of factor IX inhibitors
5. Member must be using the requested medication for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
6. Member will not use the requested medication to treat breakthrough bleeding
7. Member meets one of the following:
 - A. Has had an inadequate response, intolerance, or contraindication to compliant use of a factor IX product (e.g., Alprolix, Ixinity, Rebinyn)
 - B. Has had at least 6 acute bleeding episodes in the previous 6 months
8. Member does not have a history of coronary artery disease, venous or arterial thrombosis or ischemic disease
9. Member does not have unstable or abnormal hepatic, biliary, or renal function/disease
10. Member will not use the requested medication in combination with Alhemo or Qfitlia
- 11.

Member has not previously received treatment with a gene therapy product (e.g., Hemgenix) for the treatment of hemophilia B

12. Prophylactic use of factor IX products will be discontinued prior to starting therapy with the requested medication

Continuation of Therapy

Hemophilia A (congenital factor VIII deficiency) and Hemophilia B (congenital factor IX deficiency)

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in coverage criteria section when all of the following are met:

1. Member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds)
2. Member has no detectable or documented history of factor VIII or IX inhibitors
3. Member is not using the requested medication in combination with factor VIII products (e.g., Advate, Adynovate, Eloctate) or factor IX products (e.g., Alprolix, Ixinity, Rebinyn) for prophylactic use

Other

Hypmavzi (marstacimab-hncq) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Hypmavzi (marstacimab-hncq) 150 mg/mL prefilled syringe injection	4 syringes per 28 days	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
Hypmavzi (marstacimab-hncq) 150 mg/mL prefilled pen injection	4 pens per 28 days	Dose adjustment to 300 mg subcutaneous injection weekly in patients weighing greater than or equal to 50 kg can be considered when control of bleeding events is judged to be inadequate by the healthcare provider

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J7172 – Injection, marstacimab-hncq, 0.5 mg (effective 7/1/2025)

- C9304 – Injection, marstacimab-hncq, 0.5 mg (cancelled 7/1/2025)
- J3590 – Unclassified biologicals

REFERENCES

1. Hymovavzi [package insert]. New York, NY: Pfizer Inc.; October 2024.
2. Davide Martino, Suchitra Acharya, Andrew Palladino, Eunhee Hwang, Regina McDonald, Carrie Turich Taylor, John Teeter; 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* 2023; 142 (Supplement 1): 285.

POLICY HISTORY

Policy #: 05.05.72

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