UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2368-2
Program	Prior Authorization/Medical Necessity
Medication	Hympavzi™ (marstacimab-hncq)
P&T Approval Date	3/2025, 5/2025
Effective Date	7/1/2025

1. Background:

Hympavzi (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 inhibitors
• hemophilia B (congenital factor IX deficiency) without factor IX inhibitors

2. Coverage Criteria[a]:

A. Hemophilia A Without Inhibitors

1. Published clinical evidence shows Hympavzi is likely to produce equivalent therapeutic results as other available therapies [e.g., Hemlibra (emicizumab-kxwh)]; therefore, Hympavzi is **not medically necessary** for treatment of hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors.

   All requests for authorization will be denied. All requests for therapy must be submitted through the appeals process to the UnitedHealthcare Pharmacy appeals team for consideration.

B. Hemophilia B Without Inhibitors

1. **Initial Authorization**

   a. **Hympavzi** will be approved based on **all** of the following criteria

      (1) **One** of the following:

         (a) **Both** of the following:

            i. Diagnosis of severe hemophilia B

            -AND-

            ii. Documentation of endogenous factor IX levels less than 1% of normal factor IX (< 0.01 IU/mL)

         -OR-

         (b) **Both** of the following:

i. **One** of the following

1. **Both** of the following

a. Diagnosis of moderate hemophilia B

-AND-

b. Documentation of endogenous factor IX level ≥1% < 5% (greater than or equal to 0.01 IU/mL to less than 0.05 IU/mL)

-OR-

2. **Both** of the following

a. Diagnosis of mild hemophilia B

-AND-

b. Documentation of endogenous factor IX level ≥ 5% (greater than or equal to 0.05 IU/mL)

-AND-

ii. Submission of medical records (e.g., chart notes, laboratory values) documenting a failure to meet clinical goals (e.g., continuation of spontaneous bleeds, inability to achieve appropriate trough level, previous history of inhibitors) after a trial of prophylactic factor IX replacement products

-OR-

(c) **All** of the following:

i. Patient is currently on Hympavzi therapy

-AND-

ii. Diagnosis of hemophilia B

-AND-

iii. Patient has **not** received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the Pfizer-sponsored Hympavzi Co-Pay Savings Program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of **Hympavzi***

-AND-

(2) Patient is 12 years of age or older

-AND-

(3) Hympavzi is prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

-AND-

(4) Patient does not have a history of inhibitors to factor IX

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Pfizer-sponsored Hympavzi Co-Pay Savings Program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization of therapy will be issued for 12 months.

2. **Reauthorization**

a. **Hympavzi** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Hympavzi therapy

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Hympavzi™ [package insert]. New York, NY: Pfizer Inc., October 2024.

Program	Prior Authorization/Medical Necessity - Hympavzi (marstacimab-hncq)
Change Control	
3/2025	New program.
5/2025	Removed criteria that patient is not to receive extended half-life factor VIII replacement products for the treatment of breakthrough bleeding episodes.