UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2368-3
Program	Prior Authorization/Medical Necessity
Medication	Hympavzi™ (marstacimab-hncq)
P&T Approval Date	3/2025, 5/2025, 8/2025
Effective Date	10/1/2025

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. **Initial Authorization**

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

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

(a) Diagnosis of hemophilia A

-AND-

(b) Patient has not developed high-titer factor VIII inhibitors (i.e., patient has NOT developed factor VIII inhibitors greater than or equal to 5 Bethesda units [BU])

-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)

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.

B. Hemophilia B Without Inhibitors

1. **Initial Authorization**

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

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

(a) Diagnosis of hemophilia B

-AND-

(b) Patient has not developed high-titer factor IX inhibitors (i.e., patient has NOT developed factor IX inhibitors greater than or equal to 5 Bethesda units [BU])

-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)

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.
8/2025	Removed criteria of failure to meet clinical goals after a trial of prophylactic factor IX replacement products. Added criteria for hemophilia A without inhibitors. Clarified high titer inhibitor criteria.