

**Commercial PA Criteria**  
**Effective: January 30, 2025**

**Prior Authorization:** Hympavzi (marstacimab-hncq)

**Products Affected:** Hympavzi (marstacimab-hncq) subcutaneous injection

**Medication Description:** 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.

**Covered Uses:**

1. Hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors,
2. Hemophilia B (congenital factor IX deficiency) without factor IX inhibitors.

**Exclusion Criteria:** None

**Required Medical Information:**

1. Diagnosis
2. Medical History
3. Past therapies tried and failed

**Prescriber Restriction:** The medication is prescribed by or in consultation with a hemophilia specialist.

**Age Restriction:** The patient is  $\geq 12$  years of age.

**Coverage Duration:** 12 months

**Other Criteria:**

**1. Hemophilia A without Factor VIII Inhibitors.** Approve if the patient meets ONE of the following (A or B):

A. **Initial Therapy.** Approve if the patient meets ALL of the following (i, ii, iii, iv, v, and vi):

- i. Patient is  $\geq 12$  years of age; **AND**
- ii. Patient is using Hympavzi for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
- iii. Patient has severe hemophilia A as evidenced by a baseline (without Factor VIII replacement therapy) Factor VIII level of  $< 1\%$ ; **AND**
- iv. Patient meets **ONE** of the following (a or b):
  - a. Patient meets **BOTH** of the following [(1) and (2)]:
    - (1) Factor VIII inhibitor titer testing has been performed within the past 30 days; **AND**
    - (2) Patient does not have a positive test for Factor VIII inhibitors of  $\geq 1.0$  Bethesda units/mL; **OR**
  - b. Patient has not received Factor VIII therapy in the past; **AND**
- v. According to the prescriber, prophylactic use of Factor VIII products will not occur while using Hympavzi; **AND**  
*Note: Use of Factor VIII products for the treatment of breakthrough bleeding is permitted.*
- vi. The medication is prescribed by or in consultation with a hemophilia specialist.

B. **Patient is Currently Receiving Hympavzi.** Approve if the patient meets ALL of the following (i, ii, iii, and iv):

- i. Patient is using Hympavzi for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
- ii. According to the prescriber, prophylactic use of Factor VIII products will not occur while using Hympavzi; **AND**  
*Note: Use of Factor VIII products for the treatment of breakthrough bleeding is permitted.*
- iii. The medication is prescribed by or in consultation with a hemophilia specialist; **AND**
- iv. According to the prescriber, patient experienced a beneficial response to therapy.  
*Note: Examples of a beneficial response to therapy include a reduction in bleeding events, in the severity of bleeding episodes, in the number of bleeding events that required treatment, and/or in the number of spontaneous bleeds.*

**2. Hemophilia B without Factor IX Inhibitors.** Approve if the patient meets ONE of the following (A or B):

- A. **Initial Therapy.** Approve if the patient meets ALL of the following (i, ii, iii, iv, v, and vi):
  - i. Patient is  $\geq 12$  years of age; **AND**
  - ii. Patient is using Hympavzi for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
  - iii. Patient has moderately severe or severe hemophilia B as evidenced by a baseline (without Factor IX replacement therapy) Factor IX level  $\leq 2\%$ ; **AND**
  - iv. Patient meets **ONE** of the following (a or b):
    - a. Patient meets **BOTH** of the following [(1) and (2)]:
      - (1) Factor IX inhibitor titer testing has been performed within the past 30 days; **AND**
      - (2) Patient does not have a positive test for Factor IX inhibitors of  $\geq 1.0$  Bethesda units/mL; **OR**
    - b. Patient has not received Factor IX therapy in the past; **AND**
  - v. According to the prescriber, prophylactic use of Factor IX products will not occur while receiving Hympavzi; **AND**  
*Note: Use of Factor IX products for the treatment of breakthrough bleeding is permitted.*
  - vi. The medication is prescribed by or in consultation with a hemophilia specialist.
- B. **Patient is Currently Receiving Hympavzi.** Approve if the patient meets ALL of the following (i, ii, iii, and iv):
  - i. Patient is using Hympavzi for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
  - ii. According to the prescriber, prophylactic use of Factor IX products will not occur while using Hympavzi; **AND**  
*Note: Use of Factor IX products for the treatment of breakthrough bleeding is permitted.*
  - iii. The medication is prescribed by or in consultation with a hemophilia specialist; **AND**
  - iv. According to the prescriber, patient experienced a beneficial response to therapy.  
*Note: Examples of a beneficial response include a reduction in bleeding events, in the severity of bleeding episodes, in the number of bleeding events that required treatment, and/or in the number of spontaneous bleeding events.*

**References:**

1. Hympavzi™ subcutaneous injection [prescribing information]. New York, NY: Pfizer; October 2024.

**Policy Revision history**

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	01/30/2025