AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Hympavzi	Page:	1 of 3
Effective Date:	1/29/2025	Last Review Date:	12/6/2024
Applies to:	☒Illinois ☒Florida Kids	☒New Jersey ☒Pennsylvania Kids	☒Maryland ☒ Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Hympavzi under the patient's prescription drug benefit.

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.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Hympavzi

Policy/Guideline:

Documentation

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

Initial requests: Chart notes, lab tests documenting all of the following (where applicable):
Hemophilia A (congenital factor VIII deficiency):

- Severe factor VIII deficiency (factor VIII level of <1%)
- Absence of factor VIII inhibitors (lab test results required)

Hemophilia B (congenital factor IX deficiency):

- Moderately severe to severe factor IX deficiency (factor IX level of ≤ 2%)
- Absence of Factor IX inhibitors (lab test results required)

Continuation requests: Chart notes documenting benefit from therapy (e.g., reduced frequency or severity of bleeds).

Prescriber Specialties

The medication must be prescribed by or in consultation with a hematologist.

Initial Coverage Criteria

Hemophilia A (congenital factor VIII deficiency)

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

- Member is 12 years of age or older.
- Member is ≥ 35 kg.
- Member has severe factor VIII deficiency (defined as factor VIII level of <1%).
- Member has no dectable or documented history of factor VIII inhibitors.
- Member must be using the requested medication for routine prophylaxis to prevent or reduce the frequency of bleeding episodes.
- Member will not use the requested medication to treat breakthrough bleeding.
- Member meets ONE of the following:
  - Has had an inadequate response, intolerance, or contraindication to compliant use of a factor VIII product (e.g., Advate, Adynovate, Eloctate).
  - Has had at least 6 acute bleeding episodes in the previous 6 months.
- Member does not have a history of coronary artery disease, venous or arterial thrombosis or ischemic disease.
- Member does not have unstable or abnormal hepatic, biliary, or renal function/disease.
- Member will not use the requested medication in combination with Hemlibra.
- Member has not previously received treatment with a gene therapy product (e.g., Roctavian) for the treatment of hemophilia A.
- 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 the following criteria are met:

- Member is 12 years of age or older.
- Member is ≥ 35 kg.
- Member has moderately severe to severe factor IX deficiency (defined as factor IX level of ≤ 2%).
- Member has no detectable or documented history of factor IX inhibitors.
- Member must be using the requested medication for routine prophylaxis to prevent or reduce the frequency of bleeding episodes.
- Member will not use the requested medication to treat breakthrough bleeding.
- Member meets ONE of the following:
  - Has had an inadequate response, intolerance, or contraindication to compliant use of a factor IX product (e.g., Alprolix, Ixinity, Rebinyn).
  - Has had at least 6 acute bleeding episodes in the previous 6 months.

- Member does not have a history of coronary artery disease, venous or arterial thrombosis or ischemic disease.
- Member does not have unstable or abnormal hepatic, biliary, or renal function/disease.
- Member has not previously received treatment with a gene therapy product (e.g., Hemgenix) for the treatment of hemophilia B.
- Prophylactic use of factor IX products will be discontinued prior to starting therapy with the requested medication.

Continuation of Therapy

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

- Member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds).
- Member has no detectable or documented history of factor VIII or IX inhibitors.
- 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.

Approval Duration and Quantity Restrictions:

Approval: 12 months

Quantity Level Limit:
Hympavzi 150 mg/mL single-dose prefilled syringe: 8 syringes per 28 days
Hympavzi 150 mg/mL single-dose prefilled pens: 8 pens per 28 days

References:

1. Hympavzi [package insert]. New York, NY: Pfizer Inc.; October 2024.
2. Davide Matino, 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.