Pharmacy Drug Policy & Procedure

Policy Name:	Hemophilia Agents	Policy#:	3370P

Purpose of the Policy

The purpose of this policy is to define coverage criteria for Hympavzi (marstacimab) and Alhemo (concizumab).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Hympavzi (marstacimab) or Alhemo (concizumab) under the specialty benefit if the following criteria are met.

Criteria

1. Coverage Criteria for Hemophilia without inhibitors (Hympavzi)

1.1 Diagnosis of congenital hemophilia A (FVIII deficiency) or hemophilia B (FIX deficiency)
- Diagnosis of hemophilia A defined as an inherited deficiency of factor IX with a factor IX activity level ≤1% of normal (≤0.01 IU/dL)
- Diagnosis of hemophilia B defined as an inherited deficiency of factor IX with a factor IX activity level ≤2% of normal (≤0.02 IU/dL)

1.2 Age 12 years or older

1.3 Prescribed by or in consultation with a hematologist (blood disorder doctor)

1.4 Patient does not have evidence of factor inhibitors

1.5 Previous use of factor prophylaxis therapy for ≥ 2 months and patient will discontinue use of other prophylaxis therapy

1.6 Patient has never received any previous Hemophilia gene therapy treatment in their lifetime

1.7 Review of chart notes and labs documenting diagnosis and confirming that patient has met all of the above requirements for treatment by both a pharmacist and medical director

2. Coverage Criteria for Hemophilia with inhibitors (Alhemo)

2.1 Diagnosis of congenital hemophilia A (FVIII deficiency) or hemophilia B (FIX deficiency)
- Diagnosis of hemophilia A defined as an inherited deficiency of factor IX with a factor IX activity level ≤1% of normal (≤0.01 IU/dL)
- Diagnosis of hemophilia B defined as an inherited deficiency of factor IX with a factor IX activity level ≤2% of normal (≤0.02 IU/dL)

2.2 Documentation of inhibitors (history of inhibitor titer ≥5 Bethesda units per mL)

2.3 Age 12 years or older and weight ≥25kg

2.4 Prescribed by or in consultation with a hematologist(blood disorder doctor)

2.5 Previous use of factor prophylaxis therapy for ≥ 2 months and patient will discontinue use of other prophylaxis therapy

2.6 Patient has never received any previous Hemophilia gene therapy treatment in their lifetime

2.7 Review of chart notes and labs documenting diagnosis and confirming that patient has met all of the above requirements for treatment by both a pharmacist and medical director

3. Managed Dose Limit

3.1 Hympavzi will be limited to 150mg per week dosing (4 syringes/pens per 28 day supply)
- A loading dose of 300mg is recommended and a quantity limit override will be required for first fill to allow for 300mg loading dose
- Increase to 300mg per week dosing will require review to establish patient is not currently responding to 150mg per week dosing

3.2 Alhemo is given subcutaneously utilizing weight based dosing, no maximum dose has been established

4. Approval Period

4.1 Initial: 12 months

4.2 Reauthorization: 12 months with documented clinical benefit or stability on therapy

CPT Codes	
HCPCS Codes	

References

1. Hympavzi (marstacimab) [prescribing information]. New York, NY: Pfizer Labs; October 2024.
2. Alhemo (concizumab) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; December 2024.
3. Srivastava A, Santagostino E, Dougall A, et al; WFH Guidelines for the Management of Hemophilia panelists and co-authors. WFH guidelines for the management of hemophilia, 3rd edition. Haemophilia. 2020;26 (suppl 6):1-158.

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