

POLICY NAME	Hemophilia Agents	POLICY #	3370P
--------------------	-------------------	-----------------	--------------

Criteria

Coverage Criteria for Hemophilia without inhibitors (Hypavzi)

- ☐ **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 $\leq 1\%$ of normal (≤ 0.01 IU/dL)
 - Diagnosis of hemophilia B defined as an inherited deficiency of factor IX with a factor IX activity level $\leq 2\%$ 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

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 $\leq 1\%$ of normal (≤ 0.01 IU/dL)
 - Diagnosis of hemophilia B defined as an inherited deficiency of factor IX with a factor IX activity level $\leq 2\%$ 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 ≥ 25 kg
- ☐ **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