

POLICY NAME	Hemophilia Agents	POLICY #	3370P
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Criteria

Coverage Criteria for Hemophilia without inhibitors (Hypavzi)

- ☐ 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)
- ☐ Age 12 years or older
- ☐ Prescribed by or in consultation with a hematologist (blood disorder doctor)
- ☐ Patient does not have evidence of factor inhibitors
- ☐ Previous use of factor prophylaxis therapy for ≥ 2 months and patient will discontinue use of other prophylaxis therapy
- ☐ Patient has never received any previous Hemophilia gene therapy treatment in their lifetime
- ☐ 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)

- ☐ 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)
- ☐ Documentation of inhibitors (history of inhibitor titer ≥ 5 Bethesda units per mL)
- ☐ Age 12 years or older and weight ≥ 25 kg
- ☐ Prescribed by or in consultation with a hematologist (blood disorder doctor)
- ☐ Previous use of factor prophylaxis therapy for ≥ 2 months and patient will discontinue use of other prophylaxis therapy
- ☐ Patient has never received any previous Hemophilia gene therapy treatment in their lifetime



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