

<b>POLICY NAME</b>	Hemophilia Agents	<b>POLICY #</b>	
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## 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 ( $\leq 0.01$  IU/dL)
  - Diagnosis of hemophilia B defined as an inherited deficiency of factor IX with a factor IX activity level  $\leq 2\%$  of normal ( $\leq 0.02$  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  $\geq 2$  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 ( $\leq 0.01$  IU/dL)
  - Diagnosis of hemophilia B defined as an inherited deficiency of factor IX with a factor IX activity level  $\leq 2\%$  of normal ( $\leq 0.02$  IU/dL)
- ☐ **2.2** Documentation of inhibitors (history of inhibitor titer  $\geq 5$  Bethesda units per mL)
- ☐ **2.3** Age 12 years or older and weight  $\geq 25$ kg
- ☐ **2.4** Prescribed by or in consultation with a hematologist(blood disorder doctor)
- ☐ **2.5** Previous use of factor prophylaxis therapy for  $\geq 2$  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