

POLICY NAME	Beqvez (fidanacogene elaparvovec)	POLICY #	3371P
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Criteria

Coverage Criteria for Hemophilia B

- ☐ **1.1** Males with diagnosis of moderate or severe hemophilia B
 - Diagnosis of moderate or severe 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** Ages 18 years or older
- ☐ **1.3** Prescribed by or in consultation with a hematologist (blood disorder doctor) at a qualified hemophilia treatment center
- ☐ **1.4** Documentation of one of the following:
 - Current use of Factor IX prophylaxis therapy
 - Current or historical life-threatening hemorrhage
 - Repeated, serious spontaneous bleeding episodes o Documentation must include number of bleeds within the year prior to request
- ☐ **1.5** Patient does not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test
- ☐ **1.6** 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

Exclusion Criteria – Any of the following prevents coverage

- ☐ **2.1** Diagnosis of any other inherited or acquired hemophilia (ex: hemophilia A, hemophilia C, etc.)
- ☐ **2.2** Documented factor IX inhibitors
- ☐ **2.3** Previous treatment with any hemophilia B gene therapy