RX.PA.098.MPC Beqvez™ (Fidanacogene elaparvovec)

The purpose of this policy is to define the prior authorization process for Beqvez™ (intravenous infusion)

BEQVEZ is an adeno-associated virus vector-based gene therapy indicated for the treatment of adults with moderate to severe hemophilia B (congenital factor IX deficiency) who:

- Currently use factor IX prophylaxis therapy, or
- Have current or historical life-threatening hemorrhage, or
- Have repeated, serious spontaneous bleeding episodes, and
- Do not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test.

PROCEDURE

A. Initial Authorization Criteria:

** Please note that the provider must submit clinical documentation (chart notes, laboratory results and any other clinical support).*

Must meet all of the criteria listed under the respective diagnosis:

1. **Hemophilia B**
   - Must be an adult male, 18 years of age and older, with a diagnosis of hemophilia B
   - Must have moderately severe or severe hemophilia B as evidence by a baseline (without Factor IX replacement therapy) Factor IX level of ≤ 2% of normal;
   - Must meet ONE of the following:
     - Criteria 1 (A and B):
       a) Patient has been receiving routine prophylaxis with Factor IX therapy continuously for at least 2 months; AND
       b) According to the prescribing physician, the patient has a history of use of Factor IX therapy for at least 150 exposure days; OR
     - Criteria 2 (A and B):
       a) Patient has a history of life-threatening hemorrhage; AND
       b) On-demand use of Factor IX therapy was required for this life-threatening hemorrhage; OR
     - Criteria 3 (A and B):
       a) Patient has a history of repeated, serious spontaneous bleeding episodes; AND
       b) On-demand use of Factor IX therapy was required for these serious spontaneous bleeding episodes; AND
   - Must not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid by an approved test
   - Prescriber attests to all of the following:

  - Patient will have a negative Factor IX inhibitor titer test result performed within 30 days before receipt of Beqvez; AND
  - Patients that have a positive Factor IX titer-Bethesda titer of ≥0.6 BU (Bethesda units) testing within the last 30 days must have a follow up negative test result obtained within 2 weeks of the original positive result; AND
  - Patient does not currently have an inhibitor to Factor IX; AND
  - Patient does not have a history of Factor IX inhibitors; AND
- Prescriber attests that prophylactic therapy with Factor IX will not be given after Beqvez administration once adequate Factor IX levels have been achieved; AND
- Patient does not have an active infection with hepatitis B virus or hepatitis C virus; AND
- Patient is not currently receiving antiviral therapy for a prior hepatitis B virus or C virus exposure; AND
- Must meet one of the following (labs obtained 30 days before requesting authorization):
  - Negative test for HIV-1 and HIV-2 infection
  - If patient does have positive test results for HIV-1 or HIV-2 infection, patient must not have uncontrolled human immunodeficiency virus (CD4+ cell count ≤200/mm^3 or viral load >20 copies/mL); AND
- Patient has undergone a liver health assessment within the last 30 days and meets all of the following:
  - Alanine aminotransferase is ≤ 2 times the upper limit of normal; AND
  - Aspartate aminotransferase is ≤ 2 times the upper limit of normal; AND
  - Total bilirubin levels are ≤ 2 times the upper limit of normal; AND
  - Alkaline phosphatase levels are ≤ 2 times the upper limit of normal; AND
- Patient does not have evidence of advanced liver impairment and/or advanced fibrosis; AND
- Within the last 30 days, platelet counts were evaluated and were ≥ 100 x 10^9/L; AND
- Patient has adequate renal function as defined by meeting both of the following: an estimated creatinine clearance ≥ 30 mL/min and creatinine levels are ≤ 2 times the upper limit of normal; AND
- Prescriber attests that the patient does not have another coagulation disorder, besides hemophilia B; AND
- Prescriber attests to all of the following:
  - Following Beqvez infusion, liver enzyme testing to monitor for liver enzyme elevations will be done at least weekly for the first 4 months and periodically thereafter; AND
  - Patient will undergo monitoring for Factor IX activity at least weekly for the first 4 months and periodically thereafter; AND
- Must not have received, or is being considered for other gene therapy, or investigational cellular therapy for hemophilia.
- Must be prescribed by or in consultation with a hematologist

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Beqvez will be considered investigational or experimental for any other use and will not be covered.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	1 dose per lifetime
Reauthorization	N/A

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

Codes:

Code	Description
C9172	Injection, fidanacogene elaparvovec-dzkt, per therapeutic dose

REFERENCES

1. Beqvez (fidanacogene elaparvovec) [prescribing information]. New York, NY: Pfizer Labs; April 2024.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	*10/2024*