Corporate Medical Policy: Fidanacogene elaparvovec-dzkt (Beqvez®) **"Notification"** **POLICY EFFECTIVE APRIL 1, 2026**

Restricted Product(s):

- fidanacogene elaparvovec-dzkt (Beqvez®) intravenous infusion for administration by a healthcare professional

FDA Approved Use:

- 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

Criteria for Medical Necessity:

The restricted product(s) may be considered medically necessary when the following criteria are met:

1. The patient is 18 years of age or older; **AND**
2. The patient is male; **AND**
3. The patient has a diagnosis of **congenital hemophilia B** (also known as Factor IX deficiency, Christmas disease) **[medical record documentation required]**; **AND**
4. The patient has moderately severe to severe disease, defined by a Factor IX baseline residual level less than or equal to 2 IU/dL (≤ 2% of normal circulating Factor IX) **[medical record documentation required, including lab test]**; **AND**
5. ONE of the following **[medical record documentation required]**:
   a. The patient is on prophylactic therapy with a Factor IX agent (e.g., AlphaNine SD, Alprolix, BeneFIX, Idelvion, Ixinity, Mononine, Profilnine SD, Rebinyn, Rixubis) AND has had a minimum of 150 exposure days; **OR**
   b. The prescriber has determined that the patient requires improved protection more than is being received from current therapy (e.g., patients with increased bleeding due to severely damaged joints, patients with increased bleeding due to need for anticoagulation, elderly patients with risk for falls); **AND**
6. The patient does NOT have a history of inhibitors to Factor IX **[medical record documentation required]**; **AND**
7. The patient does NOT have active inhibitors to Factor IX (i.e., greater than or equal to 0.6 Bethesda Units [BU]) **[medical record documentation required]**; **AND**

8. The patient does NOT have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid **[medical record documentation required, including test results within the past 3 months]**; **AND**
9. ONE of the following:
    a. The patient is NOT HIV positive **[medical record documentation required, including lab tests within the past 3 months]**; **OR**
    b. The patient is HIV positive AND is well controlled (i.e., viral load less than 20 copies/mL and/or CD4+ cell count greater than 200 mm^3) **[medical record documentation required, including lab results within the past 12 months]**; **AND**
10. The patient's hepatitis B surface antigen is negative **[medical record documentation required, including lab tests within the past 3 months]**; **AND**
11. ONE of the following:
    a. The patient's hepatitis C virus (HCV) antibody is negative **[medical record documentation required, including lab tests within the past 3 months]**; **OR**
    b. The patient's HCV antibody is positive AND the patient's HCV RNA is negative **[medical record documentation required, including lab tests within the past 3 months]**; **AND**
12. The patient is NOT currently using antiviral therapy for hepatitis B or C **[medical record documentation required]**; **AND**
13. The patient does NOT have evidence of any bleeding disorder that is not related to hemophilia B **[medical record documentation required]**; **AND**
14. The patient does NOT have elevated liver function levels (i.e., alanine transaminase [ALT], aspartate aminotransferase [AST], or alkaline phosphatase [ALP] greater than 2 times the upper limit of normal; total bilirubin greater than 1.5 times the upper limit of normal) **[medical record documentation required, including lab tests within the past 3 months]**; **AND**
15. The patient does NOT have unstable liver or biliary disease (e.g., presence of ascites, hepatic encephalopathy, portal hypertension, splenomegaly, coagulopathy, hypoalbuminemia, esophageal or gastric varices, persistent jaundice, or cirrhosis) **[medical record documentation required]**; **AND**
16. The patient does NOT have significant liver fibrosis, as determined by hepatic ultrasound and elastography **[medical record documentation required]**; **AND**
17. The patient has NOT had any previous gene therapy, including the requested agent **[medical record documentation required]**; **AND**
18. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist) or has consulted with a specialist in the area of the patient's diagnosis **[medical record documentation required]**; **AND**
19. The requested dose is within FDA labeled dosing for the requested indication, and the requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below) **[medical record documentation required]**.

Duration of Approval: 180 days (one treatment course per lifetime)

Please note, for certain identified gene and cellular therapies such as fidanacogene elaparvovec-dzkt (Beqvez®), when coverage is available and the individual meets medically necessary criteria, distribution from a specialty pharmacy provider due to cost (distribution channel restriction) may be required in order for coverage to be provided. **Please contact Blue Cross NC to coordinate this therapy.

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
fidanacogene elaparvovec-dzkt (Beqvez®) intravenous (IV) infusion	Hemophilia B (congenital Factor IX deficiency) in adults	IV: 5 x 10^{11} vector genomes (vg) per kg of body weight, as a one-time single-dose infusion	J1414	**1**

***Maximum units allowed for duration of approval**
****Non-specific assigned HCPCS codes, must submit requested product NDC**

Other revenue codes that may be applicable to this policy: 0891, 0892

References: all information referenced is from FDA package insert unless otherwise noted below.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q2 annually.

April 2026: Coding change: Added the following applicable revenue codes associated with policy HCPCS code(s): 0891 (Special Processed Drugs – FDA Approved Cell Therapy) and 0892 (Special Processed Drugs – FDA Approved Gene Therapy). **Policy notification given 2/1/2026 for effective date 4/1/2026**.
January 2025: Coding change: Added HCPCS code J1414 to dosing reference table effective 1/1/2025; deleted C9172, J3490, and J3590 termed 12/31/2024.
October 2024: Coding change: Added HCPCS code C9172 to dosing reference table effective 10/1/2024; deleted C9399 termed 9/30/2024.
July 2024: Original medical policy criteria issued.