AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Beqvez™ (fidanacogene elaparvovec-dzkt) **(J1414) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

☐ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Dosing Limits:

- Quantity Limit (max daily dose) [NDC Unit]: 1 kit (based on weight chart below)
- Max Units (per dose and over time) [HCPCS Unit]: 1 kit (based on weight chart below); 1 billable unit per therapeutic dose
- Coverage will be provided for one dose and may **NOT** be renewed.

Recommended Dosage:

- The recommended dose of Beqvez is a single-dose intravenous infusion of 5×10^{11} vector genomes per kg (vg/kg) of body weight.

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- Calculate patient's dose weight:
  - Dosing is based on the patient's body mass index (BMI) in kg/m^2

Patient's BMI	Patient's Dose Weight
≤ 30 kg/m^2	Dose Weight = Actual body weight
> 30 kg/m^2	Determine using the following calculation: Dose Weight (kg) = 30 kg/m^2 x $[\text{Height (m)}]^2$

- Calculation of patient's dose volume in mL:
  - Dose weight in kilograms (kg) divided by 20 = dose in mL **(The division factor 20 represents the amount of vector genomes per mL of the Beqvez suspension (1×10^{13} vg/mL) divided by the per kilogram dose (5×10^{11} vg/kg))**
- **NUMBER OF VIALS NEEDED:** _____

Patient Dose Weight (kg)	Total number of vials per Kit	NDC
≤ 75	4	00069-2004-04
> 75 to ≤ 95	5	00069-2005-05
> 95 to ≤ 115	6	00069-2006-06
> 115 to ≤ 135	7	00069-2007-07

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member is at least 18 years of age
- ❑ Member is under the care of a specialist in hematology and/or in treating a patient population with Hemophilia B
- ❑ Member has a diagnosis of moderate to severe congenital factor IX deficiency (i.e., ≤ 2% of normal circulating factor IX), as confirmed by blood coagulation testing, for which the subject is on continuous routine factor IX prophylaxis, unless there is a contraindication or intolerance **(continuous routine prophylaxis is defined as the intent of treating with an a priori defined frequency of infusions (e.g., twice weekly, once every two weeks, etc.) as documented in the medical records; NOTE: member must be stabilized on FIX prophylaxis for at least 2 months having at least 150 days of exposure, prior to treatment with fidanacogene elaparvovec-dzkt)**
- ❑ Member has **NOT** received prior hemophilia AAV-vector–based gene therapy (e.g., etranacogene dezaparvovec)

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- ❑ Member must have at least **ONE** of the following **(check all that apply)**:
  - ❑ Currently use Factor IX prophylaxis therapy (e.g., AlphaNine SD, Alprolix, BeneFIX, Idelvion, Ixinity, Mononine, Profilnine, Rebinyn, Rixubis)
  - ❑ Have current or historical life-threatening hemorrhage
  - ❑ Have repeated, serious spontaneous bleeding episodes, (e.g., intramuscular hematomas requiring hospitalization, hemarthrosis, central nervous system (CNS) bleeding (including intracranial hemorrhage), pulmonary hemorrhage, life-threatening gastrointestinal (GI) hemorrhage and umbilical cord bleeding)
- ❑ Member has been tested and found negative for Factor IX inhibitor titers (i.e., <0.6 Bethesda Units) and does not have a prior history of inhibitors. **NOTE: if test result is positive, re-test within approximately 2 weeks. If re-test is also positive, Beqvez should not be given**
- ❑ Member Factor IX activity will be monitored periodically (e.g., weekly for 3 months) as well as presence of inhibitors if bleeding is not controlled. **NOTE: patients will continue to require exogenous Factor IX until response to Beqvez occurs**
- ❑ Member will discontinue Factor IX prophylaxis therapy upon achieving FIX levels of 5% from fidanacogene elaparvovec treatment
- ❑ Member is adeno-associated virus serotype Rh74var capsid (AAVRh74var) neutralizing antibody negative as determined by an FDA-approved or CLIA-compliant test
- ❑ Member will have baseline liver function assessed prior to and after therapy according to the monitoring schedule outlined in the product labeling with corticosteroids administered in response to elevations
- ❑ Members with preexisting risk factors for hepatocellular carcinoma (e.g., patients with cirrhosis, advanced hepatic fibrosis, hepatitis C or B, non-alcoholic fatty liver disease (NAFLD), chronic alcohol consumption, non-alcoholic steatohepatitis (NASH), and advanced age) will have abdominal ultrasound screenings and be monitored regularly (e.g., annually) for alpha-fetoprotein (AFP) elevations following administration
- ❑ Member does **NOT** have current liver-related coagulopathy, hypoalbuminemia, persistent jaundice, or cirrhosis), portal hypertension, splenomegaly, hepatic encephalopathy, hepatic fibrosis, or active viral hepatitis
- ❑ Member has been tested for HIV and does **NOT** have an active infection (i.e., either CD4+ cell count <200 mm^3 or viral load ≥ 20 copies/mL in cases of serological evidence of HIV-1 or HIV-2 infection)
- ❑ Member has been counseled on avoidance of potentially hepatoxic substances (e.g., alcohol) which may reduce the efficacy of fidanacogene elaparvovec

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Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.