ALASKA MEDICAID
Prior Authorization Criteria

Beqvez™

(fidanacogene elaparvovec-dzkt)

FDA INDICATIONS AND USAGE[1]

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:

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

APPROVAL CRITERIA[1,2]

1. Patient is 18 years of age or older **AND**;
2. Prescribed by or in consultation with a hematologist **AND**;
3. Patient has the diagnosis of hemophilia B meeting one of the above listed FDA indications **AND**;
4. Patient has moderate to severe disease as defined by factor IX levels ≤2% of normal or <2IU/dl **AND;**
5. Patient has had >150 previous exposure days to factor IX **AND;**
6. Patient does not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test
7. Patient must have no history of inhibitors to factor IX, and a screen performed within two weeks prior to administration must be negative as defined as ≤0.5 Bethesda units **AND**;
8. Patient has had a hepatic ultrasound and elastography performed prior to administration.

DENIAL CRITERIA [1,2]

1. Failure to meet approval criteria **OR**;
2. Patient currently has an active hepatitis B or hepatitis C infection **OR**;
3. Patient currently has an uncontrolled HIV infection **OR**;
4. Evidence of advanced hepatic impairment is present **OR**;
5. Patient has been previously treated with gene therapy for hemophilia B.

CAUTIONS[1]

- Monitor transaminase levels once weekly for three months following administration to monitor for possible hepatotoxicity.
- Patients with preexisting risk factors for hepatocellular carcinoma should be monitored regularly for elevated alpha-fetoprotein (AFP) and receive abdominal ultrasound screenings for five years following administration.

DURATION OF APPROVAL

- Initial Approval: 3 months
  - No reauthorization will be approved.

QUANTITY LIMIT

- One infusion per lifetime.
- HCPCS: J3590

REFERENCES / FOOTNOTES:

1. Beqvez™ (fidanacogene elaparvovec-dzkt) [package insert]. New York, NY: Pfizer, Inc.; April 2024
2. A Study to Evaluate the Efficacy and Safety of Factor IX Gene Therapy with PF-0638435 in Adult Males with Moderately Severe to Severe Hemophilia B (BENEGENE-2). Last updated 07/26/2024. Available at https://clinicaltrials.gov/study/NCT03861273