Beqvez ® (fidancogene elaparvovec-dzkt)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Beqvez (fidanocogene elaparvovec-dzkt) drug policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Beqvez (fidanocogene elaparvovec-dzk) is intended as a one-time hemophilia B treatment designed to help eligible patients make their own Factor IX.

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
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

Limitations of Use
All other indications are considered experimental/investigational and not medically necessary.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Chart notes, lab tests documenting all of the following (where applicable):
    1. Severe to moderately severe Factor IX deficiency (≤2% of normal circulating Factor IX)
    2. Absence of Factor IX inhibitors (lab test results required)
    3. Current use of Factor IX prophylaxis therapy
    4. History of life-threatening hemorrhage(s) or repeated, serious spontaneous bleeding episodes
    5. Negative adeno-associated virus serotype Rh74var (AAVRh74var) antibody test result

Prescriber Specialties

This medication must be prescribed by or in consultation with a hematologist

Criteria for Initial Approval

Hemophilia B

Authorization of 1 month for one dose total may be granted for the treatment of hemophilia B when ALL of the following criteria are met:

A. Member is 18 years of age or older
B. Member meets either of the following:
    a. Member has a negative Factor IX inhibitor test result within the past 30 days
    b. If member has a positive Factor IX inhibitor test result within the past 30 days, there must be a negative test result within 2 weeks of the initial positive result
    c. Member has severe or moderately severe Factor IX deficiency (≤2% of normal circulating Factor IX) and meets any of the following:
        i. Member is currently using Factor IX prophylactic therapy
        ii. Member has a current or history of a life-threatening hemorrhage
        iii. Member has a history of repeated, serious spontaneous bleeding episodes
C. Member has a negative adeno-associated virus serotype Rh74var (AAVRh74var) antibody test result
D. Member does not have a hypersensitivity to factor IX replacement product
E. Member is HIV negative or has a controlled HIV infection
F. Member does not have active liver-related coagulopathy, hypoalbuminemia, persistent jaundice, cirrhosis, portal hypertension, splenomegaly, hepatic encephalopathy, hepatic fibrosis or active viral hepatitis.
G. Member has not previously received gene therapy treatment

Continuation of Therapy

Repeat treatment of Beqvez for any indication is considered investigational, as the safety and efficacy beyond one dose has not been studied. The evidence is insufficient to determine the effects on net health outcomes.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia and/or evidence-based practice guidelines. Beqvez is intended for one-time single-dose intravenous infusion only.

Dosing of Beqvez is a single infusion of 5×10^{11} vector genomes per kg (vg/kg) of body weight. A dosing weight adjustment is required if a patient's BMI is more than 30 kg/m^2 and can be calculated with the following table:

Patient's BMI	Patient's Dose Weight
</= 30 kg/m^2	Dose Weight (kg) = Actual Body Weight
>30 kg/m^2	Dose Weight (kg) = 30 kg/m2 x $[\text{Height (m)}]^2$

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J1414 – Injection, fidanacogene elaparvovec-dzkt, per therapeutic dose (effective 1/1/2025)
- C9172 – Injection, fidanacogene elaparvovec-dzkt, per therapeutic dose (canceled 1/1/2025)
- J3490 – Unclassified drugs (when specified as [Beqvez] ((fidanocogene elaparvovec-dzkt))
- J3590 – Unclassified biologics (when specified as [Beqvez] (fidanocogene elaparvovec-dzkt))
- C9399 – Unclassified drugs or biologics (when specified as [Beqvez] (fidanocogene elaparvovec-dzkt))

REFERENCES

1. Beqvez [package insert]. New York, NY: Pfizer Inc.; April 2024.

POLICY HISTORY

Policy #: 05.05.56

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Revised:

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