Draft Revised Policy: Do Not Implement

Fidanacogene Elaparvovec-dzkt (Beqvez™)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.
The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit 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 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

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

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
Chart notes, lab tests documenting all of the following (where applicable):

- Severe to moderately severe Factor IX deficiency (≤2% of normal circulating Factor IX)
- Absence of Factor IX inhibitors (lab test results required)
- Current use of Factor IX prophylaxis therapy
- History of life-threatening hemorrhage(s) or repeated, serious spontaneous bleeding episodes
- Negative adeno-associated virus serotype Rh74var (AAVRh74var) antibody test result
- Baseline hematologic, hepatic, and renal assessments.

PRESCRIBER SPECIALTIES

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

COVERAGE CRITERIA ~~FOR INITIAL APPROVAL~~

Hemophilia B

Authorization of 3 ~~1~~ months for one dose total may be granted for the treatment of hemophilia B (congenital factor IX deficiency) when all of the following criteria are met:

- Member is 18 years of age or older
- Member meets both ~~either~~ of the following:
  - Member does not have a history of Factor IX inhibitors (≥ 0.6 Bethesda units [BU]).
  - Member has a negative Factor IX inhibitor test result within the past 30 days (< 0.6 Bethesda units [BU]).
    ~~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~~
- Member has severe or moderately severe Factor IX deficiency (≤2% of normal circulating Factor IX) ~~and meets any of the following:~~
- Member has a history of prophylactic Factor IX (e.g., Alprolix, Ixinity, Rebinyn) use for at least 50 exposure days.
- Member has uncontrolled disease while currently using Factor IX prophylactic therapy or has a contraindication to receiving Factor IX prophylaxis. Uncontrolled disease is defined as one of the following:
  - ~~Member is currently using Factor IX prophylactic therapy~~
  - Member has a current or history of a life-threatening hemorrhage
  - Member has a history of repeated, serious spontaneous bleeding episodes
- Member has a negative adeno-associated virus serotype Rh74var (AAVRh74var) antibody test result
- Member has the following laboratory values at baseline:
  - Hemoglobin ≥ 11 g/dL.
  - Platelets ≥ 100,000 cells/microL.
  - Creatinine ≤ 2.0 mg/dL.
- Member does not have alanine transaminase (ALT), aspartate aminotransferase (AST), and alkaline phosphatase (ALP) levels greater than 2 times the upper limit of normal (ULN).
- Member does not have a bilirubin level greater than 1.5 times the ULN (unless there is a diagnosis of Gilbert's Syndrome and member is otherwise stable).
- Member does not have current unstable liver or biliary disease as defined by the presence of ascites, hepatic encephalopathy, coagulopathy, hypoalbuminemia, esophageal or gastric varices, persistent jaundice, or cirrhosis.
- Member has undergone a hepatic ultrasound and/or elastography to rule out radiological liver abnormalities and/or sustained liver enzyme elevations.
- Member does not have cirrhosis or stage 3 or 4 liver fibrosis.
- Member meets both of the following:
  - Member does not have an active infection with hepatitis B virus or hepatitis C virus.
  - Member is not currently receiving antiviral therapy for a prior hepatitis B virus or hepatitis C virus exposure.
- Member does not have uncontrolled human immunodeficiency virus (HIV) infection as defined as a CD4 cell count ≤ 200 mm^3 or viral load > 20 copies/mL.
- Member has not previously received Beqvez or any other gene therapy previously. ~~treatment~~
- Prophylactic use of Factor IX products will not be given after Beqvez administration once adequate Factor IX levels have been achieved (note: Factor IX therapy may be given in case of surgery, invasive procedures, trauma, or bleeds in the event that Beqvez-derived Factor IX activity is deemed insufficient for adequate hemostasis).
- Provider attests that liver enzymes and Factor IX activity will be followed per the protocol outlined in the prescribing information following receipt of Beqvez infusion.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

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

EFFECTIVE DATE

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