MVP Health Care Medical Policy

Medicare Part B: Beqvez

Type of Policy:	Medical
Prior Approval Date:	N/A
Approval Date:	12/01/2024
Effective Date:	02/01/2025
Related Polices:	Hemophilia Factor Medicare Part B, Hemophilia Gene Therapy Medicare Part B

Codes Requiring Prior Authorization

J3590 fidanacogene elaparvovec (Beqvez)

Overview

Fidanacogene elaparvovec is an adeno-associated virus vector-based gene therapy indicated for the treatment of moderate to severe hemophilia B (congenital factor IX deficiency) in those who currently use factor IX prophylaxis therapy, have current or historical life-threatening hemorrhage, have repeated, or serious spontaneous bleeding episodes and who do not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test. Elevated hepatic enzymes have been reported with fidanacogene elaparvovec, and integration of liver-targeting AAV vector DNA into the genome may carry the theoretical risk of hepatocellular carcinoma development.

Please refer to relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance if available.

Indications/Criteria

A. Moderate to severe hemophilia B

Beqvez will be considered for coverage for moderate to severe hemophilia B when ALL the following criteria is met:

- Beqvez is prescribed by a board-certified hematologist or hemophilia specialist physician
- Member is biologically male
- Member has not received prior gene therapy for hemophilia B
- The member meets one of the following indication criteria:
    - Documentation that the member is currently using Factor IX prophylaxis therapy for at least 50 days OR
    - Chart notes documenting that the member has a current or historical life-threatening hemorrhage OR
    - The member has had repeated, serious spontaneous bleeding episodes requiring episodic factor IX treatment or prophylactic factor IX infusions AND
- Chart notes documenting that the member does not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA -approved test.
- Documentation that the following testing is performed prior to infusion
    - Factor IX (FIX) inhibitor test within 30 days
        - Beqvez cannot be administered to members with a positive test (≥0.6 Bethesda Units [BU] or a prior history for factor IX inhibitor)
    - HIV testing
        - Documentation that the member is not HIV positive OR member is HIV positive and is virally suppressed with anti-viral therapy
            - Beqvez cannot be administered to members with either CD4+ cell count < 200mm^3 or viral load ≥20 copies/mL
    - Liver Function test to rule out liver abnormalities
        - alanine transaminase [ALT]
        - aspartate transaminase [AST]
        - alkaline phosphatase [ALP]
        - bilirubin
        - albumin
    - Transient Liver Elastography for advanced liver fibrosis.
    - Laboratory tests for active hepatitis B or C.
        - Documentation that the member is negative for Hepatitis B and Hepatitis C

Beqvez will be approved as a one-time dose within 6 months. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

Exclusions

The use of Beqvez will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Member has received prior gene therapy
- Positive tests for antibodies to AAVRh74var
- Known hypersensitivity to factor IX replacement product
- Members with current liver-related coagulopathy, hypoalbuminemia, persistent jaundice or cirrhosis
- Active hepatitis C or hepatitis B

References

1. Beqvez. Clinical Pharmacology. Updated June 27, 2024.
2. Pfizer. (July 29, 2019-). A Study to Evaluate the Efficacy and Safety of Factor IX Gene Therapy With PF-06838435 in Adult Males With Moderately Severe to Severe Hemophilia B (BENEGENE-2). NCT03861273. Study Details | A Study to Evaluate the Efficacy and Safety of Factor IX Gene Therapy With PF-06838435 in Adult Males With Moderately Severe to Severe Hemophilia B | ClinicalTrials.gov
3. Pfizer. (November 18, 2015 to April 8, 2019). A Gene Therapy Study for Hemophilia B. NCT02484092. Study Results | A Gene Therapy Study for Hemophilia B | ClinicalTrials.gov