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Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Hematological Agents	**Original Policy Date:**	June 14, 2024
Subject:	Beqvez	**Page:**	1 of 4

Last Review Date: March 7, 2025

Beqvez

Description

Beqvez (fidanacogene elaparvovec-dzkt)

Background
Beqvez is a gene therapy designed to introduce in the transduced cells a functional copy of the factor IX gene encoding a high-activity FIX variant (FIX-R338L, hFIX Padua). The AAVRh74var capsid is able to transduce hepatocytes, the natural site of factor IX synthesis. Single intravenous infusion of Beqvez results in cell transduction and increase in circulating factor IX activity in patients with hemophilia B (1).

Regulatory Status
FDA-approved indication: 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
- 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.

Beqvez can cause hepatotoxicity. Transaminase levels should be closely monitored once or twice weekly for 4 months after Beqvez administration. Patients with preexisting risk factors for

hepatocellular carcinoma should receive abdominal ultrasound screenings and be monitored regularly for alpha-fetoprotein (AFP) evaluations in the 5 years following administration (1).

While on Beqvez therapy, factor IX activity and factor IX inhibitors should be regularly monitored for at least 4 months after administration (1).

The safety and effectiveness of Beqvez in pediatric patients less than 18 years of age have not been established (1).

Related policies
Hemgenix

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Beqvez may be considered **medically necessary** if the conditions indicated below are met.

Beqvez may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Gender assigned at birth Male

Diagnosis

Patient must have the following:

Hemophilia B

AND ALL of the following:

1. Known severe or moderately severe factor IX deficiency (≤ 2% normal circulating factor IX)
2. Patient is currently receiving factor IX prophylaxis
3. Patient has **ONE** of the following:
    a. Current or historical life-threatening hemorrhage

b. Repeated, serious spontaneous bleeding episodes

4. Patient has received a liver health assessment including enzyme testing (ALT, AST, ALP, and total bilirubin) **AND** a hepatic ultrasound and elastography
5. Prescribed by or recommended by a hematologist or a prescriber who specializes in hemophilia B

AND NONE of the following:

1. Neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test
2. History of factor IX inhibitors
3. Positive factor IX inhibitor screen results of ≥ 0.6 Bethesda Units (BU) using the Nijmegen-Bethesda assay
4. Positive HIV serological test not controlled with anti-viral therapy
5. Active hepatitis B and/or hepatitis C infection
6. Prior gene therapy for hemophilia B or under consideration for treatment with another gene therapy for hemophilia B

Prior – Approval *Renewal* Requirements

None

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity One infusion (only one PA approval for one infusion per lifetime)

Prior – Approval *Renewal* Limits

None

Rationale

Summary

Bevqez is an adeno-associated virus vector-based gene therapy indicated for the treatment of adults with Hemophilia B who currently use factor IX prophylaxis therapy, have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding

episodes. The safety and effectiveness of Beqvez in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Beqvez while maintaining optimal therapeutic outcomes.

References

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

Policy History

Date	Reason
June 2024	Addition to PA
September 2024	Annual review
March 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.