Mass General Brigham
Health Plan

Beqvez
(Fidanacogene elaparvovec-dzkt)

Policy Number: 082

	Commercial and Qualified Health Plans	MassHealth	Medicare Advantage
Authorization Required	X	X	X
No Prior Authorization			

Overview

Beqvez is an adeno-associated virus vector-based gene therapy indicated for the treatment of adult patients with moderate to severe hemophilia B (congenital factor IX deficiency).

Criteria

1. Criteria for initial approval
   A one-time, one-dose treatment of Beqvez is considered medically necessary when all of the following criteria are met:
   a. Member is 18 years of age or older; and
   b. Member has one of the following:
      i. Both of the following:
         1. Diagnosis of severe hemophilia B; and
         2. Documentation of endogenous factor IX levels less than 1% of normal factor IX (less than 0.01 IU/mL); or
      ii. All of the following:
         1. Diagnosis of moderately severe hemophilia B; and
         2. Documentation of endogenous factor IX levels greater than or equal to 1% to less than or equal to 2% (greater than or equal to 0.01 IU/mL to less than or equal to 0.02 IU/mL); and
         3. One of the following
            a. Current or historical life-threatening hemorrhage; or
            b. History of repeated spontaneous bleeding episodes; and
   c. Member is currently using factor IX prophylaxis therapy; and
   d. Member does not have a history of inhibitors to factor IX greater than or equal to 0.6 Bethesda units (BU); and
   e. Member does not screen positive for active factor IX inhibitors as defined as greater than or equal to 0.6 BU prior to administration of Beqvez; and
   f. Member does not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test; and
   g. Liver health assessments for member have ruled out any radiological liver abnormalities and/or sustained liver enzyme elevation; and
   h. Member meets both of the following:
      i. Does not have active infection of Hepatitis B virus or Hepatitis C virus (HBV or HCV); and
      ii. Is not currently receiving antiviral therapy for a prior HBV or HCV exposure; and
   i. Member does not have uncontrolled human immunodeficiency virus (HIV-1 or HIV-2); and

j. Member has not already been treated with Beqvez or any other gene therapy treatment for hemophilia B; and
k. Prescriber attests that following infusion, member's alanine aminotransferase, aspartate aminotransferase, and factor IX activity will be monitored per the monitoring schedule recommended in the prescribing information; and
l. Member is not eligible for treatment with Hemgenix.

2. Dosing and administration
   a. Beqvez is approved for a one-time, single-dose intravenous infusion only.
   b. Recommended dose is $5x10^{11}$ vector genomes per kilogram of body weight:
      i. To calculate patient's dose weight

BMI	Dose weight
≤ 30 kg/m^2	Dose weight = actual body weight
> 30 kg/m^2	Dose weight (kg) = 30 kg/m^2 x [height (m)]^2

      ii. To calculate patient's dose volume
         1. Dose weight (kg) / 20 = dose in mL
            Note: In the above equation, 20 = the amount of vector genomes per mL of the Beqvez suspension divided by the per-kilogram dose

3. Facility criteria
   a. Beqvez is prescribed by or in consultation with a hematologist; and
   b. Beqvez is administered in a Hemophilia Treatment Center (HTC) listed in the CDC's HTC directory

Exclusions
Any other use of Beqvez is considered experimental or investigational and therefore not medically necessary.

MassHealth Variation
Mass General Brigham Health Plan uses the MassHealth Drug List for coverage determinations for members of the MGB ACO. Criteria for Beqvez are found in Table 80: Anti-Hemophilia Agents.

Medicare Variation
Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for coverage determinations. **At the time of Mass General Brigham Health Plan's most recent policy review, Medicare does not have any NCDs or LCDs for gene therapy for the treatment of Hemophilia B.**

Codes

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

This list of codes applies to Commercial and MassHealth lines of business.

Authorized Code	Code Description
C9172	Injection, fidanacogene elaparvovec-dzkt, per therapeutic dose

Effective
November 12, 2024: Effective date.

References

Beqvez (fidanacogene elaparvovec) [package insert]. New York, NY: Pfizer Labs; April 2024.

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Srivastava A, Santagostino E, Dougall A, et al. WFH guidelines for the management of hemophilia, 3rd edition. Haemophilia. 2020: 26(Suppl 6): 1-158. https://doi.org/10.1111/hae.14046. Accessed 5/20/2024.