Medical Policy:

Beqvez (fidanacogene elaparvovec-dzkt kit) Intravenous Infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.413	February 27, 2025	June 28, 2024

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

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.

Length of Authorization

Coverage will be provided for one dose per lifetime.

Dosing Limits [Medical Benefit]

The recommended dose of Beqvez is a one-time (per lifetime) single dose of 5×10^{11} vector genomes per kg of body weight by intravenous infusion.

Note: Dose based on adjusted body weight for those with a body mass index > 30 kg/m^2 using the following calculation: Dose Weight (kg) = 30 kg/m2 x [Height (m)]^2

Table 1. Beqvez Multi-Vial Kits.[1]

Patient Dose Weight	Total Number of Vials per Kit	NDC Number
≤ 75 kg	4	0069-2004-04
> 75 to ≤ 95 kg	5	0069-2005-05
> 95 to ≤ 115 kg	6	0069-2006-06
> 115 to ≤ 135 kg	7	0069-2007-07

NDC – National Drug Code.

Guideline

I. INITIAL CRITERIA

1. **Hemophilia B.** Approve a one-time (per lifetime) single dose if the patient meets ALL of the following (A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, and Q):
   - A. Patient is male*; **AND**
   - B. Patient is ≥ 18 years of age; **AND**
   - C. Patient has not received a gene therapy for hemophilia B in the past **[verification in claims history required]**; **AND**

     Note: If no claim for Beqvez or Hemgenix (etranacogene dezaparvovec-drlb intravenous infusion) is present (or if claims history is not available), the prescribing physician confirms that the patient has not previously received Beqvez or Hemgenix.
   - D. Patient has moderately severe or severe hemophilia B as evidenced by a baseline (without Factor IX replacement therapy) Factor IX level ≤ 2% of normal **[documentation required]**; **AND**
   - E. Patient meets ONE of the following (i, ii, or iii):
     - i. According to the prescribing physician, the patient has a history of use of Factor IX therapy for ≥ 150 exposure days; **OR**
     - ii. Patient meets BOTH of the following (a and b):
       1. Patient has a history of life-threatening hemorrhage; **AND**
       2. On-demand use of Factor IX therapy was required for this life-threatening hemorrhage; **OR**
     - iii. Patient meets BOTH of the following (a and b):
       1. Patient has a history of repeated, serious spontaneous bleeding episodes; **AND**
       2. On-demand use of Factor IX therapy was required for these serious spontaneous bleeding episodes; **AND**
   - F. Patient does not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid by an approved test **[documentation required]**; **AND**
   - G. Patient meets ALL of the following (i, ii, and iii):
     - i. Factor IX inhibitor titer testing has been performed within 30 days **[documentation required]**; **AND**
     - ii. Patient is negative for Factor IX inhibitors **[documentation required]**; **AND**
     - iii. Patient does not have a history of Factor IX inhibitors **[documentation required]**; **AND**
   - H. Prophylactic therapy with Factor IX will not be given after Beqvez administration once adequate Factor IX levels have been achieved; **AND**

     Note: Use of episodic Factor IX therapy is acceptable for the treatment of bleeds and for surgery/procedures if needed as determined by the hemophilia specialist physician.
   - I. Patient meets BOTH of the following (i and ii):
     - i. Patient does not have an active infection with hepatitis B virus or hepatitis C virus **[documentation required]**; **AND**

ii. Patient is not currently receiving antiviral therapy for a prior hepatitis B virus or hepatitis C virus exposure **[documentation required]**; **AND**

J. According to the prescribing physician, the patient does not have uncontrolled human immunodeficiency virus infection; **AND**

K. Patient has undergone liver function testing within 30 days and meets ALL of the following (i, ii, iii, and iv):
   i. Alanine aminotransferase level is ≤ two times the upper limit of normal **[documentation required]**; **AND**
   ii. Aspartate aminotransferase level is ≤ two times the upper limit of normal **[documentation required]**; **AND**
   iii. Total bilirubin level is ≤ 1.5 times the upper limit of normal **[documentation required]**; **AND**
   iv. Alkaline phosphatase level is ≤ two times the upper limit of normal **[documentation required]**; **AND**

L. Patient does not have evidence of advanced liver impairment and/or advanced fibrosis; **AND**
   Note: For example, liver elastrography (e.g., ≥ 9 kPA) suggestive of or equal to METAVIR Stage 3 disease.

M. Within 30 days, the platelet count was ≥ 100 x 10^9/L **[documentation required]**; **AND**

N. Within 30 days, creatinine was ≤ 2.0 mg/dL **[documentation required]**; **AND**

O. The medication is prescribed by a hemophilia specialist physician; **AND**

P. Current patient body weight has been obtained within 30 days **[documentation required]**; **AND**

Q. If criteria A through P are met, approve one dose (vials in a kit) of Beqvez to provide for a one-time (per lifetime) single dose of 5 x 10^{11} vector genomes per kg of body weight by intravenous infusion **[verification required]**. Table 1 provides the number of vials per kit and the National Drug Codes (NDCs) for each kit.
   Note: Dose based on adjusted body weight for those with a body mass index > 30 kg/m^2 using the following calculation: Dose Weight (kg) = 30 kg/m^2 x [Height (m)]^2

**Documentation requirements do not apply for Medicare*

Limitations/Exclusions

1. Prior receipt of gene therapy

Applicable Procedure Codes

Code	Description
J1414	Injection, fidanacogene elaparvovec-dzkt, per therapeutic dose

Applicable NDCs

Code	Description
00069-0422-01	Beqvez 1X10E13/ML
00069-2004-xx	Beqvez 4x1mL
00069-2005-xx	Beqvez 5x1mL
00069-2006-xx	Beqvez 6x1mL
00069-2007-xx	Beqvez 7x1mL

ICD-10 Diagnoses

Code	Description
D67	Hereditary Factor Ix Deficiency

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/27/2025	Annual Review no updates
EmblemHealth & ConnectiCare	06/28/2024	New Policy

References

1. Beqvez™ intravenous infusion [prescribing information]. New York, NY: Pfizer; April 2024.