

Policy Name Fidanacogene elaparvovec-dzkt (BEQVEZ)	Policy Number MP-RX-FP-170-25	Scope <input checked="" type="checkbox"/> MMM MA <input checked="" type="checkbox"/> MMM Multihealth				
Applicable Codes						
The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.						
<table border="1"> <thead> <tr> <th data-bbox="110 714 370 745">HCPCS</th> <th data-bbox="370 714 1469 745">Description</th> </tr> </thead> <tbody> <tr> <td data-bbox="110 745 370 787">J1414</td> <td data-bbox="370 745 1469 787">Injection, fidanacogene elaparvovec-dzkt, per therapeutic dose</td> </tr> </tbody> </table>			HCPCS	Description	J1414	Injection, fidanacogene elaparvovec-dzkt, per therapeutic dose
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Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Fidanacogene elaparvovec-dzkt (BEQVEZ)

A. Criteria For Initial Approval

- i. Individual is 18 years of age or older; **AND**
- ii. Individual is diagnosed with moderate to severe hemophilia B (congenital factor IX deficiency) who:
 - a. Currently use factor IX prophylaxis therapy; **or**
 - b. Have current or historical life-threatening hemorrhage; **or**
 - c. Have repeated, serious spontaneous bleeding episodes; **and**
 - d. Does not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test; **AND**
 - e. Individual does not currently experience liver-related coagulopathy, hypoalbuminemia, persistent jaundice, or cirrhosis), portal hypertension, splenomegaly, hepatic encephalopathy, hepatic fibrosis, or active viral hepatitis; **AND**
- iii. Individual has had the appropriate liver health assessment which includes:
 - a. Liver function tests (alanine transaminase [ALT], aspartate transaminase [AST], alkaline phosphatase [ALP], bilirubin, albumin)
 - b. Laboratory tests for active hepatitis B or C.
 - c. Elastography and/or ultrasound and other laboratory assessments for liver fibrosis; **AND**
- iv. Individual must not have either a CD4+ cell count $<200\text{mm}^3$ or viral load ≥ 20 copies/mL in case of serological evidence of HIV-1 or HIV-2 infection.

B. Criteria For Continuation of Therapy

- i. **Fidanacogene elaparvovec-dzkt** is intended as a one-time therapy and repeat or continuous dosing is not supported or recommended.

C. Authorization Duration

- a. Initial Approval Duration: One time approval.

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<p>D. Conditions Not Covered <i>Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):</i></p> <ul style="list-style-type: none">i. Requests for Fidanacogene elaparvovec-dzkt (BEQVEZ) may not be approved when the above criteria are not met and for all other indications.ii. Fidanacogene elaparvovec-dzkt (BEQVEZ) should not be administered to patients with either CD4+ cell count <200mm³ or viral load ≥20 copies/mL in case of serological evidence of HIV-1 or HIV-2 infection.		

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Limits or Restrictions

A. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	
BEQVEZ (fidanacogene elaparvec-dzkt) injection	The recommended dose of BEQVEZ is 5×10^{11} vector genomes per kg (vg/kg) of body weight. Dose based on adjusted body weight for those with a BMI $>30 \text{ kg/m}^2$

Reference Information

- Dhillon S. Fidanacogene Elaparvec: First Approval. *Drugs*. 2024 Apr;84(4):479-486. doi: 10.1007/s40265-024-02017-4. Epub 2024 Mar 12. PMID: 38472707.
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- Rasko, J. E., Samelson-Jones, B. J., George, L. A., Giermasz, A., Ducore, J. M., Teitel, J. M., McGuinn, C. E., High, K. A., De Jong, Y. P., Chhabra, A., O'Brien, A., Smith, L. M., Winburn, I., & Rupon, J. (2025). Fidanacogene elaparvec for hemophilia B — a multiyear follow-up study. *New England Journal of Medicine*, 392(15), 1508–1517. <https://doi.org/10.1056/nejmoa2307159>
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- Northington MW, Rice SE, Holmes AL, Watts Alexander CS. Gene-ius at work: Hemophilia B treatment enters a new era. *Am J Health Syst Pharm*. 2025 Jan 27:zxaf005. doi: 10.1093/ajhp/zxaf005. Epub ahead of print. PMID: 39868419.

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Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Policy Inception 6/10/2025	MMM Developed Medical Policy.	7/17/2025	8/8/2025