



Pharmacy Drug Policy & Procedure

Policy Name:	Beqvez (fidanacogene elaparvovec)	Policy#:	3371P
---------------------	--	-----------------	--------------

Purpose of the Policy

The purpose of this policy is to define coverage criteria for Beqvez (fidanacogene elaparvovec).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Beqvez (fidanacogene elaparvovec) under the specialty medical benefit if the following criteria are met.

Criteria

1. Coverage Criteria for Hemophilia B

- 1.1 Males with diagnosis of moderate or severe hemophilia B
 - Diagnosis of moderate or severe hemophilia B defined as an inherited deficiency of factor IX with a factor IX activity level $\leq 2\%$ of normal (≤ 0.02 IU/dL)
- 1.2 Ages 18 years or older
- 1.3 Prescribed by or in consultation with a hematologist (blood disorder doctor) at a qualified hemophilia treatment center
- 1.4 Documentation of one of the following:
 - Current use of Factor IX prophylaxis therapy
 - Current or historical life-threatening hemorrhage
 - Repeated, serious spontaneous bleeding episodes
 - Documentation must include number of bleeds within the year prior to request
- 1.5 Patient does not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test
- 1.6 Review of chart notes and labs documenting diagnosis and confirming that patient has met all of the above requirements for treatment by both a pharmacist and medical director

2. Exclusion Criteria

- 2.1 Diagnosis of any other inherited or acquired hemophilia (ex: hemophilia A, hemophilia C, etc.)
- 2.2 Documented factor IX inhibitors
- 2.3 Previous treatment with any hemophilia B gene therapy

3. Approval Period

- 3.1 One-time approval per lifetime

CPT Codes

--	--

HCPCS Codes

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

References

1. Beqvez (fidanacogene elaparvovec) [prescribing information]. New York, NY: Pfizer Labs; April 2024.
2. Cuker A, Kavakli K, Frenzel L, et al; BENEGENE-2 Trial Investigators. Gene Therapy with Fidanacogene Elaparvovec in Adults with Hemophilia B. N Engl J Med. 2024 Sep 26;391(12):1108-1118.
3. Srivastava A, Santagostino E, Dougall A, et al. WFH Guidelines for the Management of Hemophilia, 3rd edition. Haemophilia. 2020 Aug;26 Suppl 6:1-158.
4. MASAC Recommendation Concerning Prophylaxis for Hemophilia A and B with and without Inhibitors. National Hemophilia Foundation. 2022 April 27; Rev 241.

Created Date: 02/05/25

Effective Date: 02/05/25

Posted to Website: 02/05/25

Revision Date:

DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.