Pharmacy Drug Policy & Procedure

Policy Name:	Hemgenix (etranacogene dezaparvovec)	Policy #:	3168P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Hemgenix (etranacogene dezaparvovec).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Hemgenix (etranacogene dezaparvovec) under the medical benefit when the following criteria have been 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 ≤2% of normal (≤0.02 IU/mL)

1.2 Ages 18 years or older

1.3 Prescribed by or in consultation with a hematologist (doctor of blood disorders) or hemophilia specialist

1.4 Documentation to support a current or historical life-threatening hemorrhage OR repeated, serious spontaneous bleeding episodes
- Documentation must include number of bleeds within the year prior to request of Hemgenix

1.5 Previous use of Factor IX prophylaxis therapy for ≥ 2 months

1.6 Review of chart notes and labs documenting diagnosis and confirming that patient has met all of the above requirements for treatment with Hemgenix 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 Any documented active hepatitis C infection, uncontrolled HIV infection or evidence of advanced cirrhosis

2.4 Previous treatment with any hemophilia B gene therapy

3. Approval Period

3.1 One-time approval per lifetime

CPT Codes

HCPCS Codes

J1411	Injection, etranacogene dezaparvovec-drlb, per therapeutic dose

References

1. Hemgenix (etranacogene dezaparvovec) [prescribing information]. Kankakee, IL: CSL Behring LLC; November 2022.
2. Pipe SW, Leebeek FWG, Recht M, et al. Adults with severe or moderately severe hemophilia B receiving Etranacogene Dezaparvovec in the HOPE-B phase 3 clinical trial continue to experience a stable increase in mean factor IX activity levels and durable hemostatic protection after 24 months' follow-up. Blood. 2022;140 (supplement 1):4910-4912.
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. https://www.hemophilia.org/healthcare-professionals/guidelines-on-care/masac-documents/masac-document-267-masac-recommendation-concerning-prophylaxis-for-hemophilia-a-and-b-with-and-without-inhibitors Accessed December 2022.
5. Noone D, et al. Prophylactic treatment in people with severe hemophilia B in the US: an analysis of real-world healthcare system costs and clinical outcomes. Blood. 2019;134(suppl 1):2118.

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