Health Alliance™

Pharmacy Drug Policy Checklist

POLICY NAME	Hemgenix (etranacogene dezaparvovec)	POLICY #	3168P

Criteria

Coverage Criteria for Hemophilia B

- ☐ 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)
- ☐ Ages 18 years or older
- ☐ Prescribed by or in consultation with a hematologist (doctor of blood disorders) or hemophilia specialist
- ☐ 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
- ☐ Previous use of Factor IX prophylaxis therapy for ≥ 2 months
- ☐ 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

Exclusion Criteria – Any of the following prevents coverage

- ☐ Diagnosis of any other inherited or acquired hemophilia (ex: hemophilia A, hemophilia C, etc)
- ☐ Documented factor IX inhibitors
- ☐ Any documented active hepatitis C infection, uncontrolled HIV infection or evidence of advanced cirrhosis
- ☐ Previous treatment with any hemophilia B gene therapy