Etranacogene Dezaparvovec (Hemgenix) – PA Criteria

HCPC: J1411

Etranacogene Dezaparvovec (Hemgenix) is an antihemophilic, gene therapy agent indicated for the treatment of adults with Hemophilia B. It is covered by South Dakota Medicaid following prior authorization when the patient meets the following criteria:

** All requests under this policy require SD medical director review in addition to meeting specified criteria below **

- **Initial Therapy (must meet all):**
  - Therapy is prescribed by a hematologist
  - Individual has a diagnosis of hemophilia B (congenital Factor IX deficiency) confirmed via factor IX assay
  - Disease severity is classified as moderate to severe with Factor IX levels ≤5% of normal
  - Individual was assigned male sex at birth and is ≥18 years of age
  - Individual meets **one** of the following with regard to necessity for Factor IX therapy:
    - Current use of Factor IX prophylaxis therapy (e.g., AlphaNine SD, Alprolix, BeneFIX, Idelvion, Ixinity, Mononine, Profilnine SD, Rebinyn, Rixubis) and has had a minimum of 150 exposure days OR the prescriber has determined that the patient requires improved protection in addition to current therapy due to unavoidable risks (e.g., patients with increased bleeding due to severely damaged joints, patients with increased bleeding due to need for anticoagulation, elderly patients with risk for falls)
    - Current or historical life-threatening hemorrhage
    - History of repeated, serious spontaneous bleeding episodes
  - Documentation is provided showing individual is negative for Factor IX inhibitor titers within the last 30 days
  - Documentation is provided indicating that baseline liver function tests (AST, ALT and total bilirubin) were performed and determined to be within normal limits (if there is evidence of liver abnormalities, sign off from a hepatologist indicating eligibility for Hemgenix is required before SD Medicaid will approve prior authorization request)
  - Individual has not received prior gene therapy
  - Approval duration: one time dose
- **Continuation of Therapy: not authorized**