

**SOUTH DAKOTA MEDICAID
PRIOR AUTHORIZATION CRITERIA**

Physician Administered Drugs, Vaccines, and Immunizations

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 $\leq 2\%$ of normal
- Individual was assigned male sex at birth and is ≥ 18 years of age
- Individual meets **one** of the following regarding necessity therapy:
 - Current use of Factor IX prophylaxis therapy (e.g., AlphaNine SD, Alprolix, BeneFIX, Idelvion, Ixinity, Mononine, Profilnine SD, Rebinyn, Rixubis)
 - Current or historical life-threatening hemorrhage
 - History of repeated, serious spontaneous bleeding episodes
- Documentation is submitted indicating the individual has a minimum of 150 exposure days to Factor IX therapy
- Documentation is provided showing individual is negative for Factor IX inhibitor titers within the last 30 days – If initial test was positive, subsequent negative test must be done within 2 weeks. If both initial and subsequent test are positive, Hemgenix should not be given and will not be approved. Documentation of all drawn titers must be submitted with Hemgenix request.
- Documentation is submitted indicating individual has been tested for presence of anti-adenovirus serotype 5 (AAV5) antibodies and level is < 700
- 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)
- Prescriber attests individual does not have any of the following active diseases: hepatitis B or C, HIV, decompensated cirrhosis
- Individual has not received prior gene therapy
- Approval duration: one dose

• **Continuation of Therapy: not authorized**