Valoctocogene Roxaparvovec (Roctavian) – PA Criteria

HCPC: J1412

Valoctocogene Roxaparvovec (Roctavian) is an antihemophilic gene therapy agent indicated for the treatment of Hemophilia A in adults. It is covered by South Dakota Medicaid following prior authorization when the following criteria are met:

** 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 A (congenital Factor VIII deficiency) confirmed via factor VIII assay
    - Disease is classified as severe with pre-treatment Factor VIII levels ≤1% of normal
    - Individual was assigned male sex at birth and is ≥18 years of age
    - Individual has been adherent with Factor VIII prophylaxis therapy for at least 12 months and has had at least one serious spontaneous bleeding event (within the last 12 months) while on routine prophylaxis
    - Documentation is submitted indicating the individual has a minimum of 150 exposure days to Factor VIII therapy
    - Documentation is provided showing individual is negative for Factor VIII inhibitor titers as shown by an assay level of <0.6 Bethesda units (BU) on 2 separate occasions (at least a week apart) within the last 12 months
    - Documentation is submitted indicating individual has been tested for presence of anti-adeno-associated virus serotype 5 (AAV5) antibodies and is negative
    - Individual does not have advanced liver disease (defined as ALT, AST, gamma glutamyl transferase, total bilirubin or alkaline phosphatase >1.25x upper limit of normal, international normalized ratio ≥1.4 or significant liver fibrosis (defined as prior liver biopsy showing fibrosis of 3 or 4 as rated on a scale of 1-4 on the Batts-Ludwig or METAVIR scoring systems, or an equivalent grade of fibrosis if an alternative scale was used)
    - Evidence of any bleeding disorder not related to Hemophilia A has been ruled out
    - Provider confirms that the member will discontinue any use of hemophilia A prophylactic therapy within 4 weeks after Roctavian administration
    - If female, documentation of negative pregnancy test must be submitted prior to therapy
    - Male and female members of reproductive potential must use an effective method of contraception at start of treatment and at least 6 months following Roctavian administration
    - Prescriber attests individual does not have any of the following active diseases: hepatitis B or C, or decompensated cirrhosis
    - Individual is not HIV positive
    - Individual has not received prior gene therapy
    - Approval duration: one dose
- **Continuation of Therapy:** not authorized