Atidarsagene Autotemcel (Lenmeldy) – PA Criteria

HCPC: J3391

Atidarsagene Autotemcel (Lenmeldy) is an cellular gene therapy indicated for the treatment of metachromatic leukodystrophy (MLD) in pediatric patients. 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 pediatric neurologist with expertise in the treatment of MLD
  - Individual has a diagnosis of MLD confirmed by **all** the following:
    - Arylsulfatase A (ARSA) activity below the normal range in peripheral blood mononuclear cells or fibroblasts
    - Genetic testing for biallelic ARSA pathogenic variants
    - Elevated urinary sulfatide levels
  - Individual has a diagnosis of one of the following MLD subtypes:
    - Pre-symptomatic late infantile (PSLI)
    - Pre-symptomatic early juvenile (PSEJ)
    - Early symptomatic early juvenile (ESEJ)
  - Individual can walk independently (if developmentally appropriate for age) and does not have cognitive decline as evidenced by an age-equivalent cognitive and verbal performance evaluation
  - Individual has not previously received hematopoietic stem cell gene therapy or if member has previously received hematopoietic stem cell transplant, there is no evidence of residual cells of donor origin
  - Prescriber attests individual does not have any of the following active diseases: hepatitis or HIV
  - Individual is <18 years of age and documentation is provided indicating symptom onset started before the age of 7
  - Approval duration: 1 dose
- **Continuation of Therapy: not authorized**