Voretigene neparvovec (Luxturna) – PA Criteria

HCPC: J3398

Luxturna is a prescription gene therapy product used for the treatment of patients with inherited retinal disease due to mutations in both copies of the RPE65 gene confirmed through genetic testing. It is covered by South Dakota Medicaid following prior authorization when the patient meets the following criteria:

- **Initial Therapy (must meet all):**
  - Therapy is prescribed by an ophthalmologist or retinal specialist/surgeon
  - Individual is ≥12 months of age
  - Individual has a confirmed diagnosis of biallelic RPE65 mutation-associated retinal dystrophy such as Leber's congenital amaurosis (LCA), retinitis pigmentosa (RP) or early onset severe retinal dystrophy (EOSRD)
  - Individual has not previously received RPE65 gene therapy in intended eye
  - Confirmation of sufficient viable retinal cells in each eye planned for treatment by treating physician within the past 6 months. Verification must be documented and evident by **at least one** of the following:
    - Optical coherence tomography (OCT) thickness >100um with presence of neural retina in the posterior pole
    - > 3 disc areas of retina free of atrophy and/or pigmentary degeneration in the posterior pole
    - Intact visual field within 30° of fixation as measured by a III4e isopter or equivalent
  - Injection in second eye is planned to be at least 6 days after the first eye
  - No history of intraocular surgery within the prior 6 months
  - Authorization can be given for both eyes if dates and plan are specified for each surgery OR authorization must be obtained for each eye separately
  - Approval duration: 1 dose (1 lifetime dose per eye)
- **Continuation of Therapy (must meet all): not authorized**