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
  - Documentation is submitted indicating there is sufficient viable retinal cells in each eye as evident by **at least one** of the following within the past 6 months:
    - 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
  - Individual has significant vision impairment as shown by **one** of the following:
    - Best corrected visual acuity (BCVA) of 20/60 or worse in both eyes
    - Visual field less than 20 degrees in any meridian as measured by a III4e isopter or equivalent in both eyes
  - Individual has not previously received RPE65 gene therapy
  - Injection in second eye is planned to be within a close interval, at least 6 days after the first eye
  - No history of intraocular surgery within the prior 6 months
  - Approval duration: 2 doses (1 lifetime dose per eye)
- **Continuation of Therapy (must meet all): not authorized**