Casimersen (Amondys 45) – PA Criteria

HCPC: J1426

Casimersen (Amondys 45) is an antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have confirmed genetic mutation of the DMD gene that is amenable to exon 45 skipping. It is covered with a prior authorization from South Dakota Medicaid when the following criteria are met:

- **Initial Therapy (must meet all):**
  - Prescribed by or in consultation with provider in neurology with expertise in neuromuscular disorders
  - Individual must have a diagnosis of DMD with documentation of confirmed mutation that DMD gene is amenable to exon 45 skipping (submission of medical records, genetic testing, etc.)
  - If ambulatory, documentation of baseline 6-minute walk or NorthStar Ambulatory Assessment no longer than one month prior to beginning Amondys45
  - If non-ambulatory, baseline functional level assessment with **all** the following is required, no longer than one month prior to beginning Amondys45
    - Brooke upper extremity scale (≤ 5)
    - Forced vital capacity assessment (of ≥30%)
    - Stable cardiac function with left ventricular ejection fraction (LVEF) > 40%
  - Individual is not ventilator dependent
  - Therapy is not being used in conjunction with other exon skipping therapies for DMD (ie Vyondys 53, Exondys51, Viltepso)
  - Therapy is initiated before the age of 14
  - Individual has been on a stable dose of corticosteroids for 6 months unless contraindicated or adverse effects were previously experienced
  - Approval duration: 6 months
- **Continuation of Therapy (must meet all):**
  - Must continue to meet all initial criteria
  - Continued follow-up with neurology provider and/or neuromuscular clinic
  - Documentation of response to therapy is recorded every 6 months and shows stability or improvement in **both** of the following:
    - 6-minute walk or NorthStar Ambulatory Assessment
    - Respiratory function
  - Approval duration: 6 months