

**SOUTH DAKOTA MEDICAID
PRIOR AUTHORIZATION CRITERIA**

Physician Administered Drugs, Vaccines, and Immunizations

Eteplirsen (Exondys 51) – PA Criteria

HCPC: J1428

Exondys 51 is an antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have confirmed mutation of the DMD gene that is amenable to exon 51 skipping. It is covered by South Dakota Medicaid following prior authorization when the patient meets the following criteria:

- **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 51 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 Exondys 51
 - If non-ambulatory, baseline functional level assessment with **all** the following is required, no longer than one month prior to beginning Exondys 51
 - Brooke upper extremity scale (≤ 5)
 - Forced vital capacity assessment (of $\geq 30\%$)
 - 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, Amondys 45, Viltipso)
 - 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