CareSource

# PHARMACY POLICY STATEMENT
## Georgia Medicaid

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| **DRUG NAME** | **Exondys 51 (eteplirsen)** |
| **BILLING CODE** | **J1428 (1 unit = 10 mg)** |
| **BENEFIT TYPE** | **Medical** |
| **SITE OF SERVICE ALLOWED** | **Office/Outpatient/Home** |
| **COVERAGE REQUIREMENTS** | **Prior Authorization Required (Non-Preferred Product)**<br>**QUANTITY LIMIT— see dosage allowed** |
| **LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY** | **Click Here** |

**Exondys 51 (eteplirsen) is a non-preferred product and will only be considered for coverage under the medical benefit when the following criteria are met:**

**Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.**

## DUCHENNE MUSCULAR DYSTROPHY (DMD)

**For initial authorization:**

1. **Member has a diagnosis of DMD with confirmed mutation of DMD gene that is amenable to exon 51 skipping (genetic testing results required); AND**
2. **Medication is being prescribed by or in consultation with a DMD specialist (i.e., neurologist); AND**
3. **Member is currently stable on corticosteroid for at least 3 months prior to starting therapy, unless not tolerated or contraindicated; AND**
4. **Chart notes have been provided to show that the member is able to walk independently without assistive devices.**
5. **Dosage allowed: 30 mg per kg of body weight once weekly.**

**If member meets all the requirements listed above, the medication will be approved for 6 months.**

**For reauthorization:**

1. **Chart notes must show stability or** slowed rate of decline of the member's motor function compared to **baseline; AND**
2. **Chart notes confirm that member remains able to walk independently without assistive devices.**

**If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.**

**CareSource considers Exondys 51 (eteplirsen) not medically necessary for the treatment of the diseases that are not listed in this document.**

| DATE | ACTION/DESCRIPTION |
|---|---|
| 11/29/2016 | Last revision of the policy. |
| 10/16/2017 | Policy converted into new format. No changes in criteria. |
| 05/20/2019 | Criteria on member's ambulatory status and independent walking ability added to initial authorization and reauthorization parts of the policy. |
| 06/23/2020 | Length of corticosteroid trial specified to be at least 3 months. |
| 01/14/2021 | Added prescriber requirement. Simplified ambulatory requirement. Added requirement of stability or slowed rate of decline of motor function in reauth section. |

**References:**

1. **Exondys 51 [Package Insert]. Cambridge, MA: Sarepta Therapeutics, Inc.; July 2020.**
2. **Sarepta Therapeutics. An Open-Label, Multi-Center Study to Evaluate the Safety and Tolerability of Eteplirsen in Patients With Advanced Stage Duchenne Muscular Dystrophy. NLM Identifier: NCT02286947.**
3. **Birnkrant DJ, Bushby K, Bann CM, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management [published correction appears in Lancet Neurol. 2018 Apr 4;:]. Lancet Neurol. 2018;17(3):251-267.**
4. **Gloss D, Moxley RT 3rd, Ashwal S, Oskoui M. Practice guideline update summary: Corticosteroid treatment of Duchenne muscular dystrophy: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016;86(5):465-472.**

**Effective date: 07/01/2021**
**Revised date: 01/14/2021**