

PHARMACY POLICY STATEMENT

Kentucky Medicaid

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) QUANTITY LIMIT – based on weight
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 confirmed mutation of a DMD gene that is amenable to exon 51 skipping (chart/lab notes required); AND
2. Member is currently taking a corticosteroid or has contraindication to corticosteroids.
3. **Dosage allowed:** 30 milligrams per kilogram of body weight once weekly.

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

For **reauthorization**:

1. Member must be in compliance with all other initial criteria.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 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.

References:

1. Exondys 51 [Package Insert]. Cambridge, MA: Sarepta Therapeutics, Inc.; September 2016.
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. Sarepta Therapeutics. Confirmatory Study of Eteplirsen in DMD Patients (PROMOVI). NLM Identifier: NCT02255552.
4. Sarepta Therapeutics. An Open-Label, Multi-Center Study to Evaluate the Safety and Tolerability of Eteplirsen in Early Stage Duchenne Muscular Dystrophy. NLM Identifier: NCT02420379.



Effective date: 11/08/2017
Revised date: 10/19/2017