

## PHARMACY POLICY STATEMENT

### Ohio 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 <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

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