CareSource

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 **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 stable on corticosteroid for at least 3 months, unless not tolerated or contraindicated; AND
3. Chart notes submitted confirming that the member is ambulatory and walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.) prior to beginning Exondys 51 therapy.
4. **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; AND
2. Chart notes submitted with member's status reviewed within 30 days prior to reauthorization request confirming that the member remains ambulatory and walks independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.).

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.

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.
5. Sarepta Therapeutics. Safety Study of Eteplirsen to Treat Advanced Stage Duchenne Muscular Dystrophy. NLM Identifier: NCT02286947.
6. Griggs RC, Miller JP, Greenberg CR, et al. Efficacy and safety of deflazacort vs prednisone and placebo for Duchenne Muscular Dystrophy. Neurology. 2016 Nov 15;87(20):2123-2131.

Effective date: 07/20/2020
Revised date: 06/23/2020