Eteplirsen (Exondys 51®)	Place of Service Infusion Center Administration Home Infusion Administration Office Administration Outpatient Facility Administration HCPCS: **J1428** per 10 mg

Condition listed in policy

- Duchenne muscular dystrophy (DMD)

AHFS therapeutic class: Genetic disorder treatment

Mechanism of action: Exon skipping antisense oligonucleotide

(1) Special Instructions and Pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

****CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION ****

AAAAI Guidelines 2011, MCG™ Care Guidelines, 19th edition, 2015

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO/Shared Advantage/HMO (non-direct contract)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

ADMINISTRATION OF EXONDYS 51™ IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. **Patient is initiating therapy (allowed for the first 4 infusions) with Exondys 51® or is being re-initiated on Exondys 51® after at least 6 months off therapy.** *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. **Patient has experienced a previous severe adverse event to Exondys 51® based on documentation submitted.**

3. **Patient continues to experience moderate to severe adverse events to Exondys 51® based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.**

4. **Patient is clinically unstable based on documentation submitted.**

5. **Patient is physically or cognitively unstable based on documentation submitted.**

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Exondys 51® (eteplirsen) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Duchenne muscular dystrophy (DMD)

1. Prescribed by or in consultation with a pediatric neurologist or neuromuscular specialist, **AND**
2. Diagnosis of DMD that is amenable to exon 51 skipping confirmed by genetic testing

Covered Dose
Up to 30 mg/kg IV every week

Coverage Period
Indefinitely

ICD-10:
G71.01

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Exondys 51® (eteplirsen) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
100 mg (single-dose vial)
500 mg (single-dose vial)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Exondys 51® (eteplirsen) [Prescribing Information]. Cambridge, MA: Sarepta Therapeutics; 1/2022.

(7) Policy Update

Date of last review: 2Q2023
Date of next review: 2Q2024
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee