Updated: 03/2019
PARP Approved: 05/2019

Prior Authorization Criteria

Exondys 51™ (eteplirsen)

All requests for Exondys 51™ (eteplirsen) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Exondys 51™ (eteplirsen) Prior Authorization Criteria:

Coverage may be provided with a diagnosis of Duchenne Muscular Dystrophy (DMD) and all of the following criteria is met:

- A confirmed diagnosis of DMD by submission of lab testing demonstrating mutation of the dystrophin gene amenable to exon 51 skipping;
- The member will receive concurrent corticosteroids unless contraindicated or intolerant;
- Must be prescribed by or in consultation with a neurologist who has experience in the treatment and management of DMD;
- There is documentation of a baseline evaluation, including a standardized assessment of motor function, by a neurologist with experience treating DMD;
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
    - Dose must not exceed 30mg/kg of body weight once weekly.
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
    - Exondys 51 (eteplirsen) is prescribed by or in consultation with a neurologist with experience treating DMD;
    - The member has documentation of an annual evaluation, including an assessment of motor function ability, by a neurologist who has experience in the treatment and management of DMD;
    - Based on the prescriber's assessment, the member continues to benefit from Exondys 51 (eteplirsen);
    - The member will receive concurrent corticosteroids unless contraindicated or intolerant (severe adverse reactions).
- **Reauthorization Duration of Approval:** 6 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

Gateway Health

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EXONDYS 51™ (eteplirsen)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis: ☐Duchenne Muscular Dystrophy (DMD) ☐Other: _____
ICD-10: _____

Is there lab testing demonstration the member has a mutation of the dystrophin gene amenable to exon 51 skipping?
☐ Yes ☐ No

Will the member be using Exondys 51 concurrently with corticosteroids? ☐ Yes ☐ No
If no, please explain: _____

Is a baseline evaluation included with the request? ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

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If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

MEMBER INFORMATION	
Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REAUTHORIZATION

Has an annual assessment of the member's motor function been completed? ☐ Yes ☐ No

Will the member receive concurrent corticosteroids unless contraindicated or intolerant (severe adverse reactions)?
☐ Yes ☐ No

Has the member experienced a significant improvement with treatment? ☐ Yes ☐ No
Please describe: _____
_____

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date