Updated: 03/2019
DMMA Approved: 04/2019

Request for Prior Authorization for Exondys 51 (eteplirsen)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

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 for 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;
- Documentation the member will receive concurrent corticosteroids unless contraindicated or intolerant; The patient must be a male with preserved muscle function between the ages of 7 -13 years old;
- Must be prescribed by or in consultation with a neurologist who has experience treating DMD;
- Documentation of a baseline evaluation, including a standardized assessment of motor function, by a neurologist with experience treating DMD;
- Documentation of appropriate baseline function test results must be submitted. Baseline function tests may include the following:
    - Ambulatory members: Six-minute walk test of >180 meters; **OR**
    - Non-ambulatory members: Brooke Upper Extremity Function Scale (of 5 or less) AND a Forced Vital Capacity of ≥ 30% of predicted value;
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
    - The dose must not exceed 30mg/kg of body weight once weekly.
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
    - 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;
    - Documentation the member is receiving a clinical benefit from therapy, such as improvement or stabilization of muscle strength or pulmonary function compared to baseline measures including the following:
        - Ambulatory members: Six-minute walk test of >180 meters; **OR**
        - Non-ambulatory members: Brooke Upper Extremity Function Scale (of 5 or less) AND a Forced Vital Capacity of ≥ 30% of predicted value
- **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.

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EXONDYS 51 (eteplirsen)
PRIOR AUTHORIZATION FORM- Page 1 of 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6253 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:
Health Options 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:
Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No	

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: ICD-10:
Is there lab testing demonstrating 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 including baseline motor function testing included with the request? ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

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

REAUTHORIZATION

Has the member experienced a clinical benefit with treatment? ☐ Yes ☐ No
Is an annual evaluation including motor function testing included with the request? ☐ Yes (documentation attached) ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date