Updated: 10/2020
DMMA Approved: 10/2020

Request for Prior Authorization for Duchenne Muscular Dystrophy antisense oligonucleotides
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Duchenne Muscular Dystrophy antisense oligonucleotides require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Duchenne Muscular Dystrophy antisense oligonucleotides 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 skipping of the applicable target exon
- Documentation the member will receive concurrent corticosteroids unless contraindicated or intolerant
- If requesting Exondys 51, must be age 7 to 13 years old
- If requesting Vyondys 53, must be age 6 to 15 years old
- If requesting Viltepso, must be age 4 to 18 years old
- Must be prescribed by or in consultation with a neurologist who has experience treating DMD
- Documentation of appropriate baseline function test results must be submitted. Baseline function tests include one of 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
- **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.

Table 1. DMD Medications and Target Exon

Generic Name	Brand Name	Target Exon
Eteplirsen	Exondys 51	51
Golodirsen	Vyondys 53	53
Viltolarsen	Viltepso	53

Table 2. Brooke Upper Extremity Scale

Score	Description
1	Starting with arms at the sides, the patient can abduct the arms in a full circle until they touch above the head
2	Can raise arms above head only by flexing the elbow (shortening the circumference of the movement) or using accessory muscles
3	Cannot raise hands above head, but can raise an 8-oz glass of water to the mouth
4	Can raise hands to the mouth, but cannot raise an 8-oz glass of water to the mouth
5	Cannot raise hands to the mouth, but can use hands to hold a pen or pick up pennies from the table
6	Cannot raise hands to the mouth and has no useful function of hands

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Duchenne Muscular Dystrophy Antisense Oligonucleotides
PRIOR AUTHORIZATION FORM

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) 325-6251 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 skipping?
☐ Yes ☐ No If Yes, Which Exon is amenable? _____

Will the member be using concurrent 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