HIGHMARK WHOLECARE

Updated: 05/2023
PARP Approved: 07/2023

Prior Authorization Criteria

Duchenne Muscular Dystrophy Antisense Oligonucleotides

All requests for Duchenne Muscular Dystrophy (DMD) Antisense Oligonucleotides require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

DMD antisense oligonucleotides include Exondys 51 (eteplirsen), Vyondys 53 (golodirsen), Viltepso (viltolarsen) and Amondys 45 (casimersen). New products with this classification will require the same documentation.

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 skipping of the applicable target exon
- 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
- Vyondys 53 (golodirsen) will not be used concomitantly with Viltepso (vitolarsen).
- **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;
    - Based on the prescriber's assessment, the member continues to benefit from therapy;
    - Vyondys 53 (golodirsen) will not be used concomitantly with Viltepso (vitolarsen).
    - The member is receiving concurrent corticosteroids unless contraindicated or intolerant

- **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.

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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 Wholecare Pharmacy Services. **FAX:** (888) 245-2049

If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #	Office NPI:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, 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

Is Vyondys 53 being used concomitantly with Viltepso? ☐ 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

Is Vyondys 53 being used concomitantly with Viltepso? ☐ Yes ☐ No

Is the member receiving concurrent corticosteroids unless contraindicated or intolerant? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date