HIGHMARK HEALTH OPTIONS

Updated: 05/2023
DMMA Approved: 07/2023

Request for Prior Authorization for Duchenne Muscular Dystrophy (DMD) Antisense Oligonucleotides
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

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.

Duchenne Muscular Dystrophy (DMD) Antisense Oligonucleotides Prior Authorization Criteria:

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 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 or Amondys 45, 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
- 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;
    - 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

  - Vyondys 53 (golodirsen) will not be used concomitantly with Viltepso (vitolarsen).
  - The member continues to receive 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.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product 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 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 8:00am to 7:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
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:	
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, 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
Will the member be using Vyondys 53 (golodirsen) concomitantly with Viltepso (vitolarsen)? ☐ 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
Will the member be using Vyondys 53 (golodirsen) concomitantly with Viltepso (vitolarsen)? ☐ Yes ☐ No
Will the member be using concurrent corticosteroids? ☐ Yes ☐ No, If no, please explain:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date