HIGHMARK HEALTH OPTIONS

Updated: 07/2024
Approved: 08/2024

Request for Prior Authorization for Duchenne Muscular Dystrophy (DMD) Antisense Oligonucleotides
Website Form – www.wv.highmarkhealthoptions.com
Submit request via: Fax - 1-833-547-2030.

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 with a diagnosis of 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 must be stabilized on corticosteroid therapy for at least 6 months prior to the request for coverage.
    - Documentation must be supplied detailing the prescribed steroid therapy and the patient must continue this therapy while receiving the requested drug.
    - NOTE: If the patient cannot take steroid therapy, clinical justification must be provided by the physician, otherwise the prior authorization request shall be immediately denied.
- Must be prescribed by or in consultation with a neurologist who has experience in the treatment and management of DMD
- The results of appropriate and validated baseline functional tests must be submitted with the initial request for therapy. These results will be considered valid only if taken after the patient has received corticosteroid therapy for at least 6 months. Acceptable tests may include, but are not limited to, any of the following:
    - Ambulatory members: Six-minute walk test (6MWDT) (patient must achieve > 180 meters for approval)
    - Non-ambulatory members: Brooke Upper Extremity Function Scale (of 5 or less) AND a Forced Vital Capacity of ≥ 30% of predicted value are required for approval.
- 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.

Attachments:

Table 1. DMD Medications and Target Exon

Generic Name	Brand Name	Target Exon
Eteplirsen	Exondys 51	51
Golodirsen	Vyondys 53	53
Viltolarsen	Viltepso	53
Casimersen	Amondys 45	45

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

HIGHMARK HEALTH OPTIONS

Updated: 07/2024
Approved: 08/2024

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: (833)-547-2030.**
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