

<b>Title:</b> Duchenne Muscular Dystrophy Agents	<b>Division:</b> Medical Management <b>Department:</b> Utilization Management
<b>Approval Date:</b> 10/8/17	<b>LOB:</b> Medicaid, FHP, HIV SNP, CHP, MetroPlus Gold, Market Plus, Essential, HARP
<b>Effective Date:</b> 10/8/17	<b>Policy Number:</b> UM-MP216
<b>Review Date:</b> 2/28/2022	<b>Cross Reference Number:</b>
<b>Retired Date:</b>	<b>Page 1 of 4</b>

**1. POLICY DESCRIPTION:**

Duchenne Muscular Dystrophy Agents

**2. RESPONSIBLE PARTIES:**

Medical Management Administration, Utilization Management, Integrated Care Management, Pharmacy, Claim Department, Providers Contracting.

**3. DEFINITIONS:**

Exondys 51 (eteplirsen) is indicated for Duchenne muscular dystrophy in patients who have a confirmed mutation of DMD gene that is amenable to exon 51 skipping. Eteplirsen binds to exon 51 of dystrophin pre-messenger RNA (mRNA) to exclude this exon during mRNA processing. Exon skipping allows an internally truncated dystrophin protein to be produced. Amondys 45 (casmieresen) is an antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping. Vyondys 53 (golodirsen) is an antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. Viltespo (viltolarsen) is an antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 kipping.

**4. POLICY:**

Duchenne muscular dystrophy agents will be considered medically necessary when the following conditions of coverage have been met:

**Initial Request:**

- A. Patient must have a diagnosis of DMD **AND**
- B. Documentation of genetic testing must confirm the DMD gene mutation of the patient is amenable to exon 45, 51, or 53 skipping **AND**
- C. Documentation must confirm a stable dose of corticosteroids prior to starting therapy or a documented reason not to be on corticosteroids **AND**
- D. Documentation indicates kidney function testing prior to starting therapy (except for eteplirsen) **AND**
- E. Patient is not concurrently being treated with another exon skipping therapy for DMD
- F. Dosing must be in accordance with the FDA labeling:
  - i. Exondys 51, Amondys 45, Vyondys 53: 30 mg/kg weekly

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- ii. Viltepso: 80 mg/kg weekly

*Approved for 24 weeks*

**Renewal Request**

- A. The patient has a diagnosis of Duchenne muscular dystrophy (DMD) **AND**
  - i. All initial conditions of coverage have been met.\* **AND**
  - ii. Dose is within FDA approved labeling

*Approve for 24 weeks*

**5. LIMITATIONS/ EXCLUSIONS:**

All other uses, including other forms of muscular dystrophy, are considered experimental/investigational and are not a covered benefit.

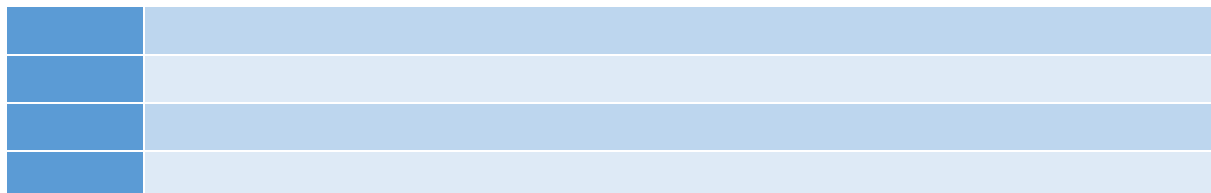
**6. APPLICABLE PROCEDURE CODES:**

CPT	Description
J1428	Injection, eteplirsen, 10 mg
J1426	Injection, casmersen, 10 mg
J1429	Injection, golodirsen, 10 mg
J1427	Injection, Viltolarsen, 10 mg

**7. APPLICABLE DIAGNOSIS CODES:**

CODE	Description
G71.01	Duchenne or Becker muscular dystrophy

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**8. REFERENCES:**

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2. Anthony K, Feng L, Arechavala-Gomez V, et al. Exon skipping quantification by quantitative reversetranscription polymerase chain reaction in Duchenne muscular dystrophy patients treated with the antisense oligomer eteplirsen. Hum Gene Ther Methods. 2012 Oct;23(5):336-45.
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11. Vyondys 53 [package insert]. Cambridge, MA: Sarepta Therapeutics, Inc: February 2021.
12. Viltepso [package insert]. Paramus, NJ; NS Pharma, Inc, March 2021
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**REVISION LOG:**

REVISIONS	DATE
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## Policy and Procedure

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Creation date	
Annual Review	10/25/19
Annual Review	9/22/2021
DOH Update Review	2/17/2022

<b>Approved:</b>	<b>Date:</b>	<b>Approved:</b>	<b>Date:</b>
<b>Glendon Henry, MD</b> <b>Senior Medical Director</b>		<b>Sanjiv Shah, MD</b> <b>Chief Medical Officer</b>	

### Medical Guideline Disclaimer:

Property of Metro Plus Health Plan. All rights reserved. The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members.

All coding and website links are accurate at time of publication.



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MetroPlus Health Plan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.