Medical Policy:

Duchenne Muscular Dystrophy Drugs (Amondys 45™, Exondys 51®, Vyondys 53®, and Viltepso®) – MEDICAID ONLY

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.349	March 26, 2025	February 28, 2022

Definitions

Duchenne Muscular Dystrophy (DMD) is an inherited disorder that results in a deficiency of dystrophin causing a loss of muscle function and weakness. DMD primarily affects males and is the most common, and severe, form of muscular dystrophy in children. Symptom onset usually occurs between the ages of 3 and 5. It is one of more than thirty forms of muscular dystrophy.

The DMD gene provides instructions for making the protein dystrophin. Dystrophin, a protein that protects muscles from deterioration, is located primarily in skeletal and heart muscle

Amondys 45 (casimersen), Exondys 51 (eteplirsen), Vyondys 53 (golodirsen), and Viltepso (viltolarsen) are all antisense oligonucleotides which bind to specific exon's of dystrophin pre-mRNA. The result yields production of a shortened, but partially functionally dystrophin protein as seen in less severe forms of muscular dystrophy.

Length of Authorization

Approvals will be granted for 12 months

Dosing Limits [Medical Benefit]

1. Amondys, Exondys, and Vyondys 30mg/kg once weekly

2. Viltepso 80mg/kg once weekly

Guideline

I. Initial Approval Criteria

1. **Duchenne Muscular Dystrophy (DMD);** Approve if all (A, B, C, E, **AND** E) are met
   - A. The patient must have a diagnosis of DMD; **AND**
   - B. The patient has documentation of genetic testing that confirms the DMD gene mutation of the patient is amenable to exon 45, 51, or 53 skipping; **AND**
   - C. The patient is on a stable dose of corticosteroids prior to starting therapy **OR** has a documented reason not to be on corticosteroids; **AND**
   - D. The patient has kidney function testing prior to starting therapy (**except for eteplirsen**); **AND**
   - E. The patient is not concurrently being treated with another exon skipping therapy for DMD.

II. Renewal Criteria

1. **Duchenne Muscular Dystrophy (DMD):**
   - A. Stabilization of disease or absence of disease progression; **AND**
   - B. Absence of unacceptable toxicity from the drug.

Limitations/Exclusions: None

Applicable Procedure Codes

Code	Description
J1429	Injection, golodirsen, 10 mg
J1426	Injection, casimersen, 10 mg
J1428	Injection, eteplirsen, 10 mg
J1427	Injection, viltolarsen; 10 mg

Applicable NDCs

Code	Description
60923-0465-02	Vyondys, single use vial; 50 mg/mL powder for injection
60923-0227-02	Amondys Injection, 100 mg/2 mL (50 mg/ mL) solution in a single-dose vial
73292-0011-01	Viltepso single-dose vials containing 250 mg/5 mL (50 mg/mL)
60923-0363-02	Exondys 51 100mg/2mL Solution J1428 Injection, Eteplirsen, 10 Mg
60923-0284-10	Exondys 51 500mg/10mL Solution J1428 Injection, Eteplirsen, 10 Mg

ICD-10 Diagnoses

Code	Description
G71.01	Duchenne or Becker muscular dystrophy

Revision History

Company(ies)	DATE	REVISION

EmblemHealth	3/26/2025	Annual Review: No Criteria Changes
EmblemHealth	3/19/2024	Annual Review: No Criteria Changes
EmblemHealth	07/11/2023	Annual Review: No Criteria Changes
EmblemHealth	2/28/2022	New Policy

References

1. Product Information: VYONDYS 53™ intravenous injection, golodirsen intravenous injection. Sarepta Therapeutics Inc (per FDA), Cambridge, MA, 2019
2. Amondys 45 intravenous Injection [package insert]. Cambridge, MA. Sarepta Therapeutics, Inc. Updated February 2021.
3. Exondys 51 [Product Information]. Cambridge, MA. Sarepta Therapeutics, Inc. Revised September 19, 2016.
4. Product Information: VILTEPSO™ intravenous injection, viltolarsen intravenous injection. NS Pharma Inc (per manufacturer), Paramus, NJ, 2020.
5. New York State Medicaid Update January 2022 Volume 38-Number 1. Available at: https://www.health.ny.gov/health_care/medicaid/program/update/2022/no01_2022-01.htm