MVP Health Care Medical Policy

Duchenne Muscular Dystrophy- Medicaid

Type of Policy: Drug Therapy
Prior Approval Date: N/A
Approval Date: 04/01/2022
Effective Date: 04/01/2022

Drugs Requiring Prior Authorization (covered under the medical benefit)

J1428 Exondys 51(eteplirsen)

J1429 Vyondys 53 (golodirsen)

J1427 Viltepso (viltolarsen)

J1426 Amondys 45 (casimersen)

Overview

Duchenne muscular dystrophy is caused by a defective gene located on the X chromosome that is responsible for the production of dystrophin. The clinical onset usually occurs between two and three years of age and may include muscle weakness, cardiomyopathy and conduction abnormalities, bone fractures, and scoliosis. Treatment with glucocorticoids such as prednisone and deflazacort is beneficial in the treatment motor function, strength, pulmonary function and reducing the risk of scoliosis.

EXONDYS 51 is 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 51 skipping. A clinical benefit of EXONDYS 51 has not been established. Continued FDA approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials. If clinical trials fail to verify clinical benefit, the FDA may initiate proceedings to withdraw approval of the drug.

Vyondys 53 is 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. Approximately 8% of the DMD population have this mutation. Continued FDA approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

Viltepso is indicated for the treatment of Duchenne Muscular Dystrophy (DMD) in patients with a confirmed mutation in the DMD gene amenable to exon 53 skipping. Continued FDA approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

Amondys 45 is 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. This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in

trials. Continued FDA approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

Indications/Criteria for Medicaid

Requests for Exondys 51, Vyondys 53, Amondys 45 and Viltepso will be reviewed when **ALL** the following criteria are met (based on New York State Department of Health Fee-For-Service criteria):

- Patient must have a diagnosis of Duchenne Muscular Disease (DMD) **AND**
- Documentation of genetic testing must confirm the DMD gene mutation of the patient is amenable to exon 45, 51 or 53 skipping **AND**
- Documentation must confirm a stable dose of corticosteroids prior to starting therapy or a documented reason not to be on corticosteroids **AND**
- Documentation indicates kidney function testing prior to starting therapy (except eteplirsen) **AND**
- Patient is not concurrently being treated with another exon skipping therapy for DMD

Exclusions

Dose above FDA approved maximum

References

1. Exondys 51 (eteplirsen) injection. Prescribing Information. Cambridge, MA: Sarepta Therapeutics, Inc. September 2016.
2. Viltepso (viltolarsen) injection, for intravenous use. Prescribing Information. Paramus, NJ: NS Pharma. August 2020.
3. Amondys 45 (casimersen) injection. Prescribing Information. Cambridge, MA: Sarepta Therapeutics, Inc. February 2021.
4. New York State Medicaid Update. January 2022. Volume 38: Number 1. Medicaid Fee-For-Service Guidance for Duchenne Muscular Dystrophy Drugs. New York State Medicaid Update - January 2022 Volume 38 - Number 1 (ny.gov)

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
MVP Medicaid Managed Care	Prior Authorization
MVP Child Health Plus	Prior Authorization
MVP Harmonious Health Care Plan	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Prior Authorization
MVP Medicare Secure HMO POS	Prior Authorization
MVP Medicare WellSelect PPO	Prior Authorization
MVP Medicare WellSelect Plus PPO	Prior Authorization
MVP Medicare Patriot Plan (PPO)	Prior Authorization
MVP SmartFund MSA	Prior Authorization

MVP DualAccess D-SNP HMO (eff. 7/1/22)	Prior Authorization
MVP DualAccess Complete D-SNP HMO (eff. 7/1/22)	Prior Authorization
MVP DualAccess Plus D-SNP HMO (eff. 7/1/22)	Prior Authorization
UVM Health Advantage Select PPO	Prior Authorization
UVM Health Advantage Secure PPO	Prior Authorization
UVM Health Advantage Preferred PPO	Prior Authorization
Gold Anywhere PPO	Prior Authorization
USACare PPO	Prior Authorization
Healthy NY	Prior Authorization
MVP Secure	Prior Authorization
MVP EPO	Prior Authorization
MVP EPO HDHP	Prior Authorization
MVP PPO	Prior Authorization
MVP PPO HDHP	Prior Authorization
Student Health Plans	Prior Authorization
ASO	See SPD
Vermont Products	
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
MVP Medicare Preferred Gold HMO POS POS	Prior Authorization
MVP Medicare Secure Plus HMO POS	Prior Authorization
MVP Medicare WellSelectPPO	Prior Authorization
MVP SmartFund MSA	Prior Authorization
UVM Health Advantage Select PPO	Prior Authorization
UVM Health Advantage Secure PPO	Prior Authorization
UVM Health Advantage Preferred PPO	Prior Authorization
Gold AnyWhere PPO	Prior Authorization
MVP VT HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP Secure	Prior Authorization
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	

***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
Retro Review	Retrospective Review Required
Not Covered	Service is not a covered benefit.
See SPD	See Specific Plan Design