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Viltepso™(viltolarsen) (Intravenous)

Effective Date: 12/1/2020
Review Date: 11/9/2020, 4/15/2021, 3/3/2022, 2/1/2023, 9/14/2023, 12/07/2023, 01/04/2024, 08/28/2024
Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

I. Length of Authorization

Authorization is valid for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC unit]:
- Viltepso 250 mg vial: 36 vials per 7 days

B. Max Units (per dose and over time) [HCPCS Unit]:

Duchenne muscular dystrophy

- 920 billable units (9200 mg) every 7 days

III. Summary of Evidence

Viltepso (viltolarsen) 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. Clinical trials evaluating its efficacy and safety have demonstrated positive outcomes in improving motor function and slowing disease progression in patients with DMD. Commonly reported adverse events include injection-site reactions, fever, and headache.

IV. Initial Approval Criteria [1-6]

MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Coverage is provided in the following conditions:

Universal Criteria

- Patient is not on concomitant therapy with other DMD-directed antisense oligonucleotides (e.g., Exondys 51 (eteplirsen), Vyondys 53 (golodirsen), Amondys 45 (casimersen), etc.); **AND**
- Patient has never received and will not receive therapy with Elevidys (delandistrogene moxeparvovec-rokl) within 6 months of this request; **AND**
- Patient does not have symptomatic cardiomyopathy; **AND**
- Patient serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio will be measured prior to start of therapy and during treatment (monthly urine dipstick with serum cystatin C and urine protein-to-creatinine ratio every three months); **AND**

Duchenne muscular dystrophy (DMD) † Φ

- Patient must have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping; **AND**
- Patient has been on a stable dose of corticosteroids, unless contraindicated or intolerant, for at least 6 months; **AND**
- Patient retains meaningful voluntary motor function (e.g., patient is able to speak, manipulate objects using upper extremities, ambulate, etc.); **AND**
- Patient should be receiving physical and/or occupational therapy; **AND**
- Baseline documentation of one or more of the following:
    - Dystrophin level
    - 6-minute walk test (6MWT) or other timed function tests (e.g., time to stand [TTSTAND], time to run/walk 10 meters [TTRW], time to climb 4 stairs [TTCLIMB])
    - Upper limb function (ULM) test
    - North Star Ambulatory Assessment (NSAA)
    - Forced Vital Capacity (FVC) percent predicted

† FDA-labeled indication(s), ‡ Compendia recommended indication(s); Φ Orphan Drug

V. Renewal Criteria

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), etc. identified in section IV; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: renal toxicity/proteinuria, etc.; **AND**
- Patient has responded to therapy compared to pretreatment baseline in one or more of the following (not all-inclusive):

- Increase in dystrophin level
- Stability, improvement, or slowed rate of decline in 6MWT or other timed function tests (e.g., time to stand [TTSTAND], time to run/walk 10 meters [TTRW], time to climb 4 stairs [TTCLIMB])
- Stability, improvement, or slowed rate of decline in ULM test
- Stability, improvement, or slowed rate of decline in NSAA
- Stability, improvement, or slowed rate of decline in FVC% predicted
- Improvement in quality of life

VI. Dosage/Administration

Indication	Dose
Duchenne muscular dystrophy	The recommended dosage of Viltepso is 80 mg/kg administered once weekly as a 60-minute intravenous infusion.

VII. Billing Code/Availability Information

HCPCS Code:

- J1427– Injection, viltolarsen, 10 mg

NDC:

- Viltepso 250 mg/5 mL single-dose vial: 73292-0011-xx

VIII. References

1. Viltepso [package insert]. Paramus, NJ; NS Pharma, Inc.; August 2023. Accessed July 2024.
2. Topaloglu H, Gloss D, Moxley RT 3rd, et al. Practice guideline update summary: Corticosteroid treatment of Duchenne muscular dystrophy: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016 Jul 12;87(2):238.
3. Bushby K, Finkel R, Birnkrant DJ, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and pharmacological and psychosocial management. Lancet Neurol; 2010 Jan; 9(1):77-93.
4. Bushby K, Finkel R, Birnkrant DJ, et al. Diagnosis and management of Duchenne muscular dystrophy, part 2: implementation of multidisciplinary care. Lancet Neurol; 2010

Jan; 9(2):177-189.

5. Clemens PR, Rao VK, Connolly AM, et al; CINRG DNHS Investigators. Safety, Tolerability, and Efficacy of Viltolarsen in Boys With Duchenne Muscular Dystrophy Amenable to Exon 53 Skipping: A Phase 2 Randomized Clinical Trial. JAMA Neurol. 2020 May 26. doi: 10.1001/jamaneurol.2020.1264. [Avail at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7251505/]
6. Bushby K, Connor E. Clinical outcome measures for trials in Duchenne muscular dystrophy: report from International Working Group meetings. Clin Investig (Lond). 2011;1(9):1217-1235

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G71.01	Duchenne or Becker muscular dystrophy

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT,	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Policy Rationale:
Viltepso was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Viltepso according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.