Viltepso (viltolarsen)

Override(s)	Approval Duration
Prior Authorization	6 months

Medications	Dosing Limit
Viltepso (viltolarsen)	80 mg/kg once weekly

APPROVAL CRITERIA

Initial requests for Viltepso (viltolarsen) may be approved if the following criteria are met:

I. Individual has a confirmed diagnosis of Duchenne muscular dystrophy (DMD); **AND**
II. Documentation is provided that individual has a genetic mutation that is amenable to exon 53 skipping; **AND**
III. Individual is age 4-9 years (NCT02740972) (Clemens 2020); **AND**
IV. Individual is using a corticosteroid; **AND**
V. Documentation is provide that individual is ambulatory; **AND**
VI. Individual is able to complete the following assessments: (NCT02740972, NCT04060199; Clemens 2020)
    A. Time to stand from supine; **AND**
    B. Time to run/walk 10 meters; **AND**
    C. Time to climb 4 stairs**; AND**
VII. Individual will not use with any other exon skipping agents for DMD (including but not limited to Vyondys 53).

Continuation of therapy with Viltepso (viltolarsen) may be approved if the following criterion are met:

I. Criteria above were met at initiation of therapy; **AND**
II. Documentation is provided that individual remains ambulatory (with or without needing an assistive device, such as a cane or walker).

Requests for Viltepso (viltolarsen) may not be approved when the criteria above are not met and for all other indications.

Key References:

1. Kole R, Krieg AM. Exon skipping therapy for Duchenne muscular dystrophy. *Ad Drug Del Rev*. 2015; 87:140-107.
2. Watanabe N, Nagata T, Satou Y, et.al. NS-065/NCNP-01: An antisense oligonucleotide for potential treatment of exon 53 skipping in Duchenne Muscular Dystrophy. *Molecular Therapy: Nucleic Acids*. 2018; 13:442-449.
3. Clemens PR, Rao VK, Connolly AM, et.al. 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*. May 2020. doi:10.1001/jamaneurol.2020.1264.
4. Viltepso [package insert]. Paramus, NJ; NS Pharma, Inc; 2020.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.