Mass General Brigham
Health Plan

Viltepso (vitolarsen)
Effective 05/01/2021

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Duchenne's Muscular Dystrophy is a form of rapidly worsening muscular dystrophy. DMD is caused by a defective gene for dystrophin.

Viltepso 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.

Coverage Guidelines
Authorization may be reviewed for members new to the plan who are currently receiving treatment with Viltepso excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted when documentation is provided for patients who meet the following criteria:

1. The member has a diagnosis of Duchenne Muscular Dystrophy
2. The member has genetic testing was confirming the diagnosis of DMD and to identify the specific type of DMD gene mutation.
3. The DMD gene mutation is amenable to exon 53 skipping (refer to examples in Appendix).
4. The member will be initiating treatment with Viltepso prior to age of 10
5. The member is able to walk independently without assistive devices.
6. The member dose will not exceed 80 mg/kg.
7. The requested medication will be not used Vyondys 53 (golodirsen)

<u>Continuation of Therapy</u>
Reauthorization may be granted when ALL of the following criteria are met:

1. The member has demonstrated a response to therapy as evidenced by remaining ambulatory (e.g., not wheelchair dependent).

2. The member will not exceed a dose of 80 mg/kg.
3. The requested medication will be not used concomitantly with Vyondys 53 (golodirsen)

Limitations

1. Initial approvals with be granted for 6 months
2. Reauthorizations will be granted for 12 months.

Appendix

Examples of DMD gene mutations (exon deletions) amenable to exon 53 skipping

1. Deletion of exon 52
2. Deletion of exon 45-52
3. Deletion of exon 47-52
4. Deletion of exon 48-52
5. Deletion of exon 49-52
6. Deletion of exon 50-52

References

1. Viltepso [package insert]. Paramus, NJ: NS Pharma, Inc.; August 2020.
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. Mol Ther Nucleic Acids. 2018;13:442–449. doi:10.1016/j.omtn.2018.09.017

Review History

3/17/2021 – Created and Reviewed at March P&T. Effective 05/01/2021.