Mass General Brigham
Health Plan

Viltepso (vitolarsen)
Effective 04/01/2023

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations			
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions			

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. Confirmed out of frame deletion in the DMD gene that is amenable to exon 53 skipping
3. Prescriber is a neuromuscular neurologist or consult notes from a neuromuscular neurology office are provided
4. Member is ambulatory as defined by a current six-minute walk test (6MWT – distance walked in six minutes in meters) ≥ 200 meters (tests must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner):
5. Dosing is appropriate (80 mg/kg intravenously every week)
6. Member has received a corticosteroid for at least 3 months prior and documentation that the member will continue to use a corticosteroid in combination with the requested agent or a demonstrated contraindication to corticosteroids

7. Member has at least a baseline measurement for ALL of the following timed function tests as shown in medical records (tests must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner):
    a. Timed 10-meter walk/run (time in seconds)
    b. Timed floor (supine) to stand (time in seconds)
    c. Timed 4-step descend (time in seconds)
    d. Timed 4-step climb (time in seconds)
    e. Timed sit to stand (time in seconds)

Continuation of Therapy

Reauthorization may be granted when ALL of the following criteria are met:

1. Member remains ambulatory as defined by a current six-minute walk test (6MWT-distance walked in six minutes in meters) of ≥ 200 meters
2. Member has a stable or improving pattern of 6MWTs as shown in medical records with results of a pretreatment baseline and all interim results. All previous 6MWTs results must be included
3. Dosing remains appropriate
4. Member continues to take a corticosteroid in combination with the requested agent (or demonstrated contraindication to corticosteroids)
5. Member has a stable or improving pattern of observed performance on at least 2 of the following five timed function tests as shown in medical records. All results for all tests must be included with the date of performance. Performance and measurement of test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner.
    a. Timed 10-meter walk/run (time in seconds)
    b. Timed floor (supine) to stand (time in seconds)
    c. Timed 4-step descend (time in seconds)
    d. Timed 4-steb climb (time in seconds)
    e. Timed sit to stand (time in seconds)

Limitations

1. Initial approvals and reauthorizations will be granted for 3 months.

References

1. Viltepso® [package insert]. Paramus (NJ): NS Pharma, Inc. 2021 Mar.
2. Birnkrant DJ, Bushby K, Bann CM, Apkon SD, Blackwell A, Brumbaugh D, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management. Lancet Neurol. 2018 Mar;17(3):251-267.
3. Darras BT. Duchenne and Becker muscular dystrophy: Clinical features and diagnosis. In: Dashe JF (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2018 [cited 2020 Jan 1]. Available from: http://www.utdol.com/utd/index.do.
4. Center for Drug Evaluation and Research. Medical Review: Application number 206488Orig1s000. Food and Drug Administration. 2016 Sep [cited 2019 Mar 5]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/206488Orig1s000MedR.pdf.

Review History

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

02/08/2023 - Reviewed and updated for Feb P&T. Matched MH UPPL criteria. Viltepso was added to the pharmacy benefit. Updated criteria to include provider specialty, 6MWT requirement, appropriate dosing, trial requirement of a corticosteroid, and baseline measurement for each timed function tests. Updated reauth criteria, approval durations to 3 months, and references. Effective 4/1/23.