Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Viltepso™ (viltolarsen)

Effective: January 13, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration - Approved Indications

Viltepso (viltolarsen) is an antisense oligonucleotide 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.

This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with Viltepso. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Viltepso for Members, when **ALL** the following clinical criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of Duchenne muscular dystrophy with medical records confirming a mutation of the Duchenne muscular dystrophy gene that is amenable to exon 53 skipping

   Note: *Common Duchenne muscular dystrophy deletions that are theoretically amenable to exon 53 skipping include: 52, 45-52, 47-52, 48-52, 49-52, and 50-52.*

AND

2. The prescribing physician is a neurologist or a provider who specializes in the treatment of Duchenne muscular dystrophy

AND

3. Documentation of **one (1)** of the following:
   a. Member has been receiving a stable dose of corticosteroids for a period of at least 6 months and will continue to utilize them in combination with Viltepso
   b. Member has a contraindication to corticosteroids

AND

4. Viltepso will be not used concomitantly with any other disease-modifying therapies for Duchenne Muscular Dystrophy (e.g. golodirsen [Vyondys 53])

Reauthorization Criteria

1. Documented diagnosis of Duchenne muscular dystrophy with medical records confirming a mutation of the Duchenne muscular dystrophy gene that is amenable to exon 53 skipping

   Note: *Common Duchenne muscular dystrophy deletions that are theoretically amenable to exon 53 skipping include: 52, 45-52, 47-52, 48-52, 49-52, and 50-52*.

AND

2. The prescribing physician is a neurologist or a provider who specializes in the treatment of Duchenne muscular dystrophy

AND

3. Documentation of **one (1)** of the following:
   a. Member continues to utilize corticosteroids in combination with Viltepso
   b. Member has a contraindication to corticosteroids

AND

4. Documentation that based on the prescriber's assessment, the Member continues to benefit from Viltepso, documented by a standardized assessment of motor function or respiratory function

AND

5. Viltepso will be not used concomitantly with any other disease-modifying therapies for Duchenne Muscular Dystrophy (e.g. golodirsen [Vyondys 53])

Limitations

- Initial approval of Viltepso will be authorized for six (6) months. Reauthorization of Viltepso will be provided in 12-month intervals.
- Members new to the plan stable on Viltepso should be reviewed against Reauthorization Criteria.
- The Plan will not authorize the use of Viltepso in Members with Duchenne muscular dystrophy who do not have a confirmed mutation of the Duchenne muscular dystrophy gene that is amenable to exon 53 skipping. Common Duchenne muscular dystrophy deletions that are theoretically amenable to exon 53 skipping include: 52, 45 -52, 47-52, 48-52, 49-52, and 50-52.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J1427	Injection, viltolarsen, 10 mg

References

1. 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;9:77-93.
2. Bushby K, Finkel R, Birnkrant DJ, et al. Diagnosis and management of Duchenne muscular dystrophy, part 2: implementation of multidisciplinary care. Lancet Neurol. 2010;9:177-89.
3. Gloss D, Moxley RT, Ashwal S, et al. Practice guideline update summary: Corticosteroid treatment of duchenne muscular dystrophy. Neurology. 2016;86:465-72.
4. Viltepo (viltolarsen) [package insert]. Paramus, NJ: NS Pharma, Inc.; March 2021.
5. 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

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- October 10, 2023: Extended reauthorization period to 12 months (effective 11/1/2023)
- September 10, 2024: No changes.
- January 14, 2025: No changes (eff 1/14/25)
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- January 13, 2026: No changes
- February 2026: Administrative update to remove Carelink from template.

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.