Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

Viltepso® (viltolarsen)

Effective: April 1, 2025

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

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

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

Pharmacological approaches to treating DMD slow disease progression by reducing inflammation, increasing muscle strength, improving forced vital capacity, delaying scoliosis, and reducing the need for surgery. Corticosteroids are considered the standard of care, delaying loss of ambulation and respiratory decline by several years. Exon-skipping antisense oligonucleotide therapies slow the progression of DMD in about 30% of patients but have not been proven to improve survival or functional outcomes.

Approval of Viltepso was based on an increase in a surrogate marker, dystrophin production in skeletal muscle. No functional outcome improvement has been shown in the clinical trials for Viltepso.

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 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

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J1427	Injection, viltolarsen, 10 mg

References

1. Gloss D, 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;86(5):465-472.
2. Birnkrant DJ, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management. Lancet Neurol. 2018;17(3):251-267.
3. Birnkrant DJ, et al. Diagnosis and management of Duchenne muscular dystrophy,part 2: respiratory, cardiac, bone health, and orthopaedic management. Lancet Neurol. 2018;17(4):347-361.
4. Birnkrant DJ, et al. Diagnosis and management of Duchenne muscular dystrophy, part 3: primary care, emergency management, psychosocial care, and transitions of care across the lifespan. Lancet Neurol. 2018;17(5):445-455.
5. American Academy of Neurology. Evidence-Based Guideline Summary: Evaluation, Diagnosis, and Management of Congenital Muscular Dystrophy. Published March 2015. Accessed March 4, 2021.
6. Viltepso (viltolarsen) [package insert]. Paramus, NJ: NS Pharma, Inc.; March 2021.

Approval And Revision History

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

September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

Subsequent endorsement date(s) and changes made:

- November 14, 2023: Removed Limitation Any indications other than FDA-approved indications are considered experimental or investigational and will not be approved by the health plan. Updated provider specialty requirements to The prescribing physician is a neurologist or a provider who specializes in the treatment of Duchenne muscular dystrophy. Added corticosteroid prerequisite. Added Viltepso will be not used concomitantly with any other disease-modifying therapies for Duchenne Muscular Dystrophy (e.g. golodirsen [Vyondys 53]). Minor wording updates. (eff 2/1/2024).
- November 2023: Administrative Updates: Rebranded from Tufts Health Unify to Tufts Health One Care for 2024 and administrative update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- September 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 10/1/24)
- September 10, 2024: No changes.
- February 11, 2025: No changes. Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template (eff 4/1/25).
- March 2025: Joint Medical Policy and Health Care Services UM Committee review (eff 4/1/25).

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines 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.