

Viltolarsen (Viltepso™)

Place of Service
Infusion Center Administration
Home Infusion Administration
Office Administration
Outpatient Facility Infusion Administration
Hospital Outpatient Facility Administration

HCPCS: J1427 per 10 mg

Condition listed in policy (see criteria for details)

- [Duchenne muscular dystrophy \(DMD\)](#)

AHFS therapeutic class: Genetic disorder treatment; antisense oligonucleotide

Mechanism of action: antisense oligonucleotide that binds to exon 53 of dystrophin pre-mRNA resulting in exon exclusion to produce truncated dystrophin protein in patients with genetic mutations that are amenable to exon 53 skipping.

(1) Special Instructions and Pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Viltepso™ (viltolarsen) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Duchenne muscular dystrophy (DMD)

1. Prescribed by a pediatric neurologist or neuromuscular specialist, **AND**
2. Diagnosis of DMD that is amenable to exon 53 skipping confirmed by genetic testing

Covered Dose

Up to 80 mg/kg IV every week

Coverage Period

Indefinitely

ICD-10:

G71.01

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Viltepso® (viltolarsen) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How Supplied:

- 250 mg/5 mL (single-dose vial)

(6) References

- AHFS®. Available by subscription at <http://www.lexi.com>
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Viltipso® (viltolarsen) [Prescribing information]. Paramus, NJ: NS Pharma, Inc.; 3/2021.

(7) Policy Update

Date of last review: 2Q2023

Date of next review: 2Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*