Viltolarsen (Viltepso®)	Place of Service Infusion Center Administration Home Infusion Administration Office Administration Outpatient Facility Infusion Administration Hospital Outpatient Facility Administration* [*Prior authorization required – see section (1)] 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.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO/Shared Advantage/HMO (non-direct contract)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG™ Care Guidelines, 19th edition, 2015

ADMINISTRATION OF VILTEPSO® IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. **Patient is receiving their first injection of Viltepso or is being re-initiated on Viltepso after at least 6 months off therapy.** *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. **Patient has experienced a previous severe adverse event to Viltepso™ based on documentation submitted.**

3. **Patient continues to experience moderate to severe adverse events to Viltepso™ based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.**

4. **Patient is clinically unstable based on documentation submitted.**

5. **Patient is physically or cognitively unstable based on documentation submitted.**

(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
- Viltepso® (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.