JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP117
		Effective Date	01/15/2025
		Approval Date	07/17/2024
	Subject **Viltepso**	*Supersedes Date*	N/A
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Viltepso

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I. POLICY

A. Viltepso (viltolarsen) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. Viltepso may be approved for patients who meet the following:
   1. Documentation has been submitted showing the following:
      a. Diagnosis of Duchenne Muscular Dystrophy (DMD) confirmed by genetic testing with identification of the specific type of DMD gene mutation
      b. The DMD gene mutation is amenable to exon 53 skipping. Examples include the following (not all-inclusive list):
         I. Deletion of exon 52
         II. Deletion of exon 45-52
         III. Deletion of exon 47-52
         IV. Deletion of exon 48-52
         V. Deletion of exon 49-52
         VI. Deletion of exon 50-52
      c. Treatment with Viltepso is initiated before the age of 10
      d. Patient is able to walk independently without assistive devices
      e. Patient meets one of the following scenarios:
         I. Patient has not previously received gene replacement therapy for DMD (e.g., Elevidys)
         II. Patient has previously received gene replacement therapy for DMD (e.g., Elevidys) and has experienced a worsening in clinical status since receiving gene replacement therapy (e.g., decline in ambulatory function)
      f. Patient will not exceed a dose of 80 mg/kg once weekly
      g. Viltepso will not be used concomitantly with golodirsen (Vyondys 53)

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 6 months of therapy
B. Continuation of therapy may be approved in 12-month intervals with documentation showing the following:
   1. Patient has had a beneficial response to therapy evidenced by remaining ambulatory (e.g., not wheelchair dependent)
   2. Patient will not exceed a dose of 80 mg/kg once weekly
   3. Viltepso will not be used concomitantly with golodirsen (Vyondys 53)
C. Limitation: Patients who were previously established on Viltepso and subsequently administered gene replacement therapy (e.g., Elevidys) must meet all initial criteria prior to re-starting Viltepso

IV. EXCLUSIONS

A. Viltepso will not be covered for the following:
   1. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSE

Please refer to the FDA-approved prescribing information, or clinical guidelines, for indication-specific dosing details.

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Injection, viltolarsen, 10 mg	J1427

VII. REFERENCES

1. Viltepso [prescribing information]. Paramus, NJ: NS Pharma, Inc.; March 2021.
2. 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.

VIII. APPROVALS

Signature on file at JHHP

DATE OF REVISION	SUMMARY OF CHANGE
07/17/2024	Policy creation
01/15/2025	Removed prescriber specialty requirement

Review Date: 07/17/2024

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