



Coding and Billing Guide

Coding Information and Sample CMS-1500 and
UB-04 Claim Forms for VILTEPSO® (viltolarsen)



Coding and Billing Guide for VILTEPSO® (viltolarsen)

Accurate and appropriate coding and billing can help avoid delays in claims processing and facilitate timely reimbursement. NS Support is pleased to provide this Guide as an educational reference offering general coding and billing information to facilitate medically appropriate patients' access to VILTEPSO.

This Guide is divided into 2 main sections:

- [Home infusion and physician office](#)
- [Hospital outpatient departments \(HOPD\)](#)

Each section includes a list of coding information and an appropriate sample claim form.

Each healthcare provider is ultimately responsible for the selection of appropriate codes for individual patients. This Guide lists possible coding options, which may vary by payor organization, and should be used for reference purposes only. NS Support cannot guarantee that the billing codes listed will result in coverage or payment for VILTEPSO or reimbursement for any claims. Please verify all codes with the patient's insurance prior to submitting claims.

While NS Support has made every effort to be current as of the publication of this Guide, the information may not be as current when you view it. Similarly, all Current Procedural Terminology (CPT®) and Healthcare Common Procedure Coding System (HCPCS) codes are supplied for informational purposes only. Additional information may exist, and actual coverage and reimbursement decisions are made by individual payor organizations.

Providers should contact the applicable payor organization for specific information on coding and billing requirements. You may also contact NS Support for coding and billing information for VILTEPSO.

Call 833-NSSUPRT (833-677-8778), Monday-Friday, 8 AM–8 PM ET.

Avoiding Denied Claims

Potential causes of delayed or denied claims may include:

- Invalid or missing codes
- Incorrect product information
- Missing or incorrect National Drug Code, prior authorization number, or National Provider Identifier
- Incorrect patient identifier information (eg, insurance identification number, date of birth)
- Failure to follow payor-specific requirements

Glossary of terms used in this Guide

Average Sales Price (ASP) – ASPs serve as the basis of Medicare payment for Part B covered drugs. ASP is based on the manufacturer’s sales to all purchasers in the United States for a calendar quarter divided by the total number of units sold by a manufacturer in that quarter. The ASP excludes price concessions, with limited exceptions.¹

Codes for drug administration – CPT® codes are the most widely accepted medical nomenclature used to report medical procedures and services under public and private health insurance programs.²

Coding units – Providers need to accurately calculate the number of billing units for drugs. This varies depending on the specific drug and dose. For example, one billing unit may equal 10 mg of a specific drug; if 40 mg of the drug is administered, this represents 4 units.³

Dual eligibility – Some patients are eligible for both Medicare and Medicaid. In these cases, Medicare pays first, and Medicaid may then cover medical costs that Medicare may not cover or partially covers. Dual eligible benefits vary by state.⁴

HCPCS codes – Drugs are typically reported using product-specific HCPCS codes (eg, J codes) assigned by the Centers for Medicare & Medicaid Services (CMS). When a medication has been assigned a specific J code, use of the J code when submitting claims may facilitate timely reimbursement.⁵

ICD-10-CM diagnosis codes – All parties covered by the Health Insurance Portability and Accountability Act (HIPAA), not just providers who bill Medicare or Medicaid, are required to use the *International Classification of Diseases, 10th Revision, Clinical Modification* (ICD-10-CM) diagnosis codes to document patient diagnoses.⁶

Modifiers – It may be necessary to use a modifier to indicate that a service or procedure has been altered by some specific circumstance but not changed in its definition/code.² In addition, HCPCS Modifiers JG “Drug or biological acquired with 340B drug pricing program discount” or TB “Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes” are used to identify 340B-acquired drugs provided by a hospital outpatient department.⁷ HCPCS modifier JW is used to document drug amount discarded/not administered to any patient.

National Drug Code (NDC) – Payor requirements regarding the use of the 10- or 11-digit NDC may vary. Electronic data exchange generally requires the use of the 11-digit NDC.⁸

Revenue codes – Many payors require the use of American Hospital Association (AHA) revenue codes to bill for services provided in hospital outpatient departments. Revenue codes consist of a leading zero followed by 3 other digits and are used on claim forms to assign costs to broad categories of hospital revenue centers.⁹

Same-day evaluation and management (E/M) services – It may be necessary to provide E/M services on the same day as a drug administration procedure. Depending on the payor, E/M services that are medically necessary, separate, and distinct from the infusions procedure (CPT® codes 99211-99215) and documented appropriately are generally covered.¹⁰ Use of CPT® Modifier 25 “Significant, Separately Identifiable E/M Service by the Same Physician or Other Qualified HCP on the Same Day of the Procedure or Other Service” may be required.²

INDICATION

VILTEPSO is 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.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions: Kidney toxicity was observed in animals who received viltolarsen. Although kidney toxicity was not observed in the clinical studies with VILTEPSO, the clinical experience with VILTEPSO is limited, and kidney toxicity, including potentially fatal glomerulonephritis, has been observed after administration of some antisense oligonucleotides. Kidney function should be monitored in patients taking VILTEPSO. Serum creatinine may not be a reliable measure of kidney function in DMD patients.

Serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio should be measured before starting VILTEPSO. Consider also measuring glomerular filtration rate before starting VILTEPSO. During treatment, monitor urine dipstick every month, and serum cystatin C and urine protein-to-creatinine ratio every three months.

Urine should be free of excreted VILTEPSO for monitoring of urine protein. Obtain urine either prior to VILTEPSO infusion, or at least 48 hours after the most recent infusion. Alternatively, use a laboratory test that does not use the reagent pyrogallol red, which has the potential to generate a false positive result due to cross reaction with any VILTEPSO in the urine. If a persistent increase in serum cystatin C or proteinuria is detected, refer to a pediatric nephrologist for further evaluation.

Adverse Reactions: The most common adverse reactions include upper respiratory tract infection, injection site reaction, cough, and pyrexia.

For more information about VILTEPSO, visit www.VILTEPSO.com and see full [Prescribing Information](#).

Coding and Billing Guide for Home infusion and physician office

Depending upon Medicare/Medicaid and individual private payor policies, some combination of the following codes may be appropriate for describing provision of therapy with VILTEPSO® (viltolarsen) on home infusion/physician office claims. Providers should check the policy of each payor organization for specific information on coding and billing requirements.

Coding Information for VILTEPSO		Location on CMS-1500 Claim Form
NDC for VILTEPSO (11-digit)¹¹		
73292-0011-01	VILTEPSO (250 mg/5 mL [50 mg/mL] single-dose vial)	Item 19
Diagnosis Code: ICD-10-CM¹²		
G71.01	Duchenne or Becker muscular dystrophy ^h	Item 21
Example CPT® Codes for Drug Administration and E/M Services		
Physician Office²		
96365 ^a	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial up to 1 hour. Some payors may require this code.	Item 24D
96366 ^a	Each second infusion and subsequent infusions of the same drug/substance; use in conjunction with 96365	
99211-99215 ^{b-d}	Evaluation and Management (E/M) Services	
Home Infusion^{2,13}		
99601 ^a	Home infusion/specialty drug administration, per visit (up to 2 hours)	Item 24D
99602 ^e	Home infusion/specialty drug administration, per visit (up to 2 hours)	
S9379 ^f	Home infusion therapy, infusion therapy, not otherwise classified, per diem	
HCPCS Code for VILTEPSO¹⁴		
J1427 ^g	Injection, Viltolarsen; bills in 10 mg units HCPCS modifier JW is used to document drug amount discarded/not administered to any patient.	Item 24D
Coding Unit for VILTEPSO¹³		
Number of units provided	1 unit of J1427 = 10 mg	Item 24G

^aIndividual payor policies for the use of drug administration codes 96365, 96366, and 99601 may vary.

^bUse of E/M codes requires documentation of medically appropriate services performed on the same day as the infusion.

^cRefer to E/M code instructions.

^dUse of CPT® Modifier 25 “Significant, Separately Identifiable E/M Service by the Same Physician or Other Qualified HCP on the Same Day of the Procedure or Other Service” may be required.

^eFor any additional administration hours needed (up to 2 hours), use 99602.

^fSome commercial/private payors may require use of S9379; check with these payors before use of this code.

^gPayors may require additional information along with the specified drug code.

^hVILTEPSO is not indicated for Becker muscular dystrophy.

Coding and Billing Guide for Hospital outpatient departments (HOPD)

Depending upon Medicare/Medicaid and individual private payor policies, some combination of the following codes may be appropriate for describing provision of therapy with VILTEPSO® (viltolarsen) on HOPD claims. Providers should check the policy of each payor organization for specific information on coding and billing requirements.

Coding Information for VILTEPSO		Location on UB-04 Claim Form
Revenue Codes: AHA^{9,a}		
0636 ^b	Drugs requiring detailed coding	Locator Boxes 42 & 43
0250	General pharmacy	
0260	General intravenous therapy	
NDC for VILTEPSO (11-digit)¹¹		
73292-0011-01	VILTEPSO (250 mg/5 mL [50 mg/mL] single-dose vial)	Locator Box 80
HCPCS Code for VILTEPSO¹⁴		
J1427 ^c	Injection, Viltolarsen; bills in 10 mg units HCPCS modifier JW is used to document drug amount discarded/not administered to any patient.	Locator Box 44
Example CPT[®] Codes for Drug Administration and E/M Services²		
96365 ^{d,e}	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial up to 1 hour. Some payors may require this code.	Locator Box 44
96366 ^{d,e}	Each second infusion and subsequent infusions of the same drug/substance; use in conjunction with 96365	
99211-99215 ^{f,h}	Evaluation and Management (E/M) Services	
Coding Unit for VILTEPSO^{13,i}		
Number of units provided	1 unit of J1427 = 10 mg	Locator Box 46
Diagnosis Code: ICD-10-CM¹²		
G71.01	Duchenne or Becker muscular dystrophy ^j	Locator Box 66

^aThis is not an all-inclusive list of revenue codes. Use of revenue codes will vary by institution.

^bUse revenue code 0636 to align HCPCS J1427 with the appropriate category on the hospital cost report.

^cWhen applicable, report either Modifier JG “Drug or biological acquired with 340B drug pricing program discount” or Modifier TB “Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes.”

^dPayors may require additional information along with the specified drug code.

^eIndividual payor policies for the use of drug administration codes 96365 and 96366 may vary.

^fUse of E/M codes requires documentation of medically appropriate services performed on the same day as the infusion.

^gRefer to E/M code instructions.

^hUse of CPT[®] Modifier 25 “Significant, Separately Identifiable E/M Service by the Same Physician or Other Qualified HCP on the Same Day of the Procedure or Other Service” may be required.

ⁱBased on expected HCPCS J1427 billing unit of 10 mg.

^jVILTEPSO is not indicated for Becker muscular dystrophy.

Sample UB-04 Claim Form (for illustration purposes only)

Locator Boxes 42 & 43
AHA revenue codes

Locator Box 43
Include a detailed drug description with the N4 indicator first, the 11-digit NDC (with no hyphens) second, the unit of measurement qualifier third (eg, ML for milliliters), and the unit quantity fourth

Locator Box 44
CPT® code: Use 96365 and/or 96366, as required

Locator Box 44
HCPCS code for VILTEPSO® (viltolarsen)
Use modifier JW with J1427 on a separate line to document drug amount discarded

Locator Box 46
Number of units provided (1 unit of J1427 = 10 mg)

Locator Box 66
ICD-10 diagnosis code G71.01 for DMD

Locator Box 80
Include drug name, total dose administered, NDC for VILTEPSO, and route of administration

1 Anytown Hospital 160 Main Street Anytown, Anystate 01010		2 Pay-to-name Pay-to-address Pay-to-city/state		3a PAT CNTL # XX-XXXX		4 TYPE OF BILL	
5 MED. REC. # DOE 1234-97		6 FED. TAX NO. 010001010		7 STATEMENT COVERS PERIOD FROM		7 THROUGH	
8 PATIENT NAME John B. Doe (ID)		9 PATIENT ADDRESS 3914 Spruce St.		10 BIRTHDATE 02/02/16		11 SEX M	
12 ADMISSION DATE		13 HR		14 TYPE		15 SRC	
16 DHR		17 STAT		18		19	
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Identifying options to help patients afford treatment

Our goal is simple: we want to help your patients get treatment with VILTEPSO® (viltolarsen), regardless of their insurance or financial situation.

Patients with commercial insurance

Eligible patients with commercial insurance coverage for treatment with VILTEPSO are automatically enrolled in the NS Support Co-pay Assistance Program.^a

- Savings on their deductible, co-pay, and co-insurance costs for their medication costs for VILTEPSO
- Automatic program re-enrollment every calendar year, if eligible

Simplified co-pay assistance

A personalized program card will be mailed to patients and their caregivers.

Remind patients and those who care for them to always bring the program card to treatment appointments.

Claim Submission Process

Medical Benefit Claims:

- Fax the following documents to 888-212-0482:
 - Completed claim form (Universal UB-04 or CMS-1500 Claim Form)
 - Primary EOB showing itemized claim from the patient’s commercial insurance company with the cost for VILTEPSO listed separately

Pharmacy Benefit Claims:

- Submit the transaction to AssistRx using claims information on the front of the patient’s Co-pay Assistance Program Card
- If primary commercial prescription insurance exists, input card information as secondary coverage and transmit using the COB segment of the NCPDP transaction. Applicable discounts will be displayed in the transaction response

If the infusion provider cannot or does not participate in the program, or if the patient has already paid for treatment, the patient may submit a claim using a Patient Reimbursement Form, available at VILTEPSO.com. Completed forms can be faxed to 888-212-0482, uploaded to the NS Support Patient Engagement Site, or mailed to: NS Support, PO Box 7613, Overland Park, KS 66207-9941.

Co-pay ID

Identifies a patient enrolled in NS Support Co-pay Assistance Program



Questions: Call NS Support at 833-NSSUPRT (833-677-8778), Monday–Friday, 8 AM–8 PM ET.

^aThe NS Support Co-pay Assistance Program is for eligible patients who have commercial insurance that covers a portion of the medication and administration costs for VILTEPSO. Other restrictions apply. See full [Eligibility Requirements & Terms and Conditions](#).

Additional cost support options

Patients with Medicaid and other government-funded insurance

We can provide information about government-funded insurance, including government health plan options for VILTEPSO® (viltolarsen), such as:

- Supplemental Security Income (SSI)
- Medicaid
- Children’s Health Insurance Plan (CHIP)
- Medicare

For patients who are uninsured

The NS Support Patient Assistance Program (PAP) can help uninsured patients in financial need navigate the complex and often confusing access and reimbursement landscape.

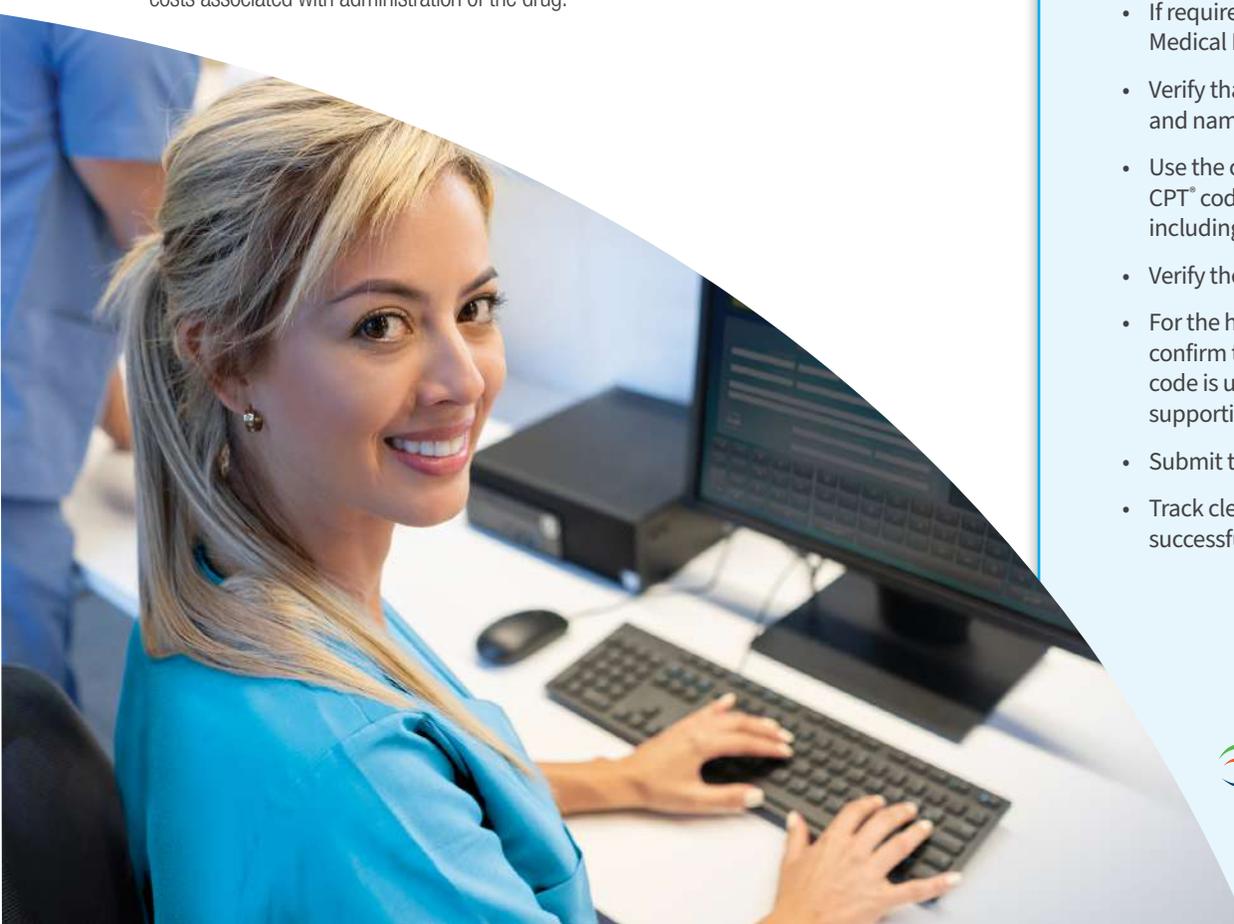
- Patients who meet program requirements may be able to receive VILTEPSO at no charge for up to one year^a
 - Restrictions apply. See full [Eligibility Requirements & Terms and Conditions](#)

We can also provide information about independent foundations and programs that may offer financial assistance.

^aPatients, parents, or legal representatives may be responsible for additional costs associated with administration of the drug.

Reminders for Submitting Claims

- Determine if VILTEPSO is covered as a medical or pharmacy benefit and if there are any prior authorization requirements
- Accurately complete and submit the prior authorization form, if required
- Ensure medical records include full and proper documentation of the patient’s history, prior therapy, and rationale for treatment
- Specify the correct number of product units on the appropriate claim form (see pages 4 through 7 for instructions on filling out claim forms)
- If required, include a Letter of Medical Necessity
- Verify that all identification numbers and names are entered correctly
- Use the correct ICD-10-CM codes, CPT® codes, and HCPCS codes, including modifiers, if applicable
- Verify the proper use of billing codes
- For the hospital outpatient setting, confirm that the correct revenue code is used with the appropriate supporting HCPCS code
- Submit the claim in a timely fashion
- Track clearinghouse claims to ensure successful transmission



Patient Assistance Program

Eligibility Requirements & Terms and Conditions

- You must be a citizen or a permanent resident of the US or its territories and reside in the US or its territories.
- You must not be covered, in whole or in part, by government health insurance (eg, Medicare, Medicaid, CHIP, TRICARE, Indian Health Service, Department of Defense, or other federal or state assistance programs).
- You are being treated as an outpatient by a licensed healthcare professional in the US and have been prescribed VILTEPSO® (viltolarsen) by a licensed healthcare professional.
- You must be uninsured.
- Your income must not exceed 4 times the Federal Poverty Level based on household size (Federal Poverty Level Guidelines available at <https://aspe.hhs.gov/poverty-guidelines>).
- You may be required to submit accurate and complete documentation (eg, most recent federal tax return, W-2, pay stubs, Social Security Award Letter or check) as requested by NS Pharma, Inc. each year to validate levels of income.
- You and your prescriber may not bill, charge, seek credit for, or otherwise submit any claim for reimbursement for VILTEPSO provided through the Patient Assistance Program to any third-party payor.
- NS Pharma, Inc. and NS Support have the right to verify your eligibility, including the right to audit any information provided on the Patient Start Form, and the right to contact you to confirm receipt of medications.
- NS Pharma, Inc. and NS Support in their sole discretion can determine your eligibility to participate in the NS Support Patient Assistance Program.
- Approved patients will be eligible to receive assistance for one year from the date of enrollment for each enrollment form submitted.
- The Patient Assistance Program covers only the cost of VILTEPSO and not the cost of any infusion services or healthcare provider visits, which are the sole responsibility of the patient.
- The program requires that you (or your parent, guardian, or legal representative) re-enroll every year by completing an NS Support Patient Assistance Program Form for VILTEPSO and provide proof of income.
- A notice regarding re-enrollment will be sent to you (or your parent, guardian, or legal representative) 45 days in advance of the expiration of your participation in the program.
- Patients (or their parent, guardian, or legal representative) must notify NS Support of any changes in their total gross income and/or health insurance status.
- Patients who no longer satisfy the eligibility requirements will be immediately withdrawn from the NS Support Patient Assistance Program, including patients participating in the NS Support Patient Assistance Program who become eligible for Medicaid coverage.
- NS Pharma, Inc. has the right to modify, alter, or cancel the NS Support Patient Assistance Program at any time without prior notification.

For more information about VILTEPSO, visit www.VILTEPSO.com and see full [Prescribing Information](#).

Co-pay Assistance Program

Eligibility Requirements & Terms and Conditions

- You must be a citizen or a permanent resident of the US or its territories and reside in the US or its territories where co-pay assistance is not prohibited.
- You must not be enrolled in government health insurance (eg, Medicare, Medicaid, Indian Health Service, Veterans Administration, Department of Defense, or any other federal or state government assistance programs). If you move or switch from commercial insurance to any government-funded insurance, you will no longer be eligible.
- You are being treated as an outpatient by a licensed healthcare provider in the US and have been prescribed VILTEPSO® (viltolarsen) by a licensed healthcare provider.
- You currently have private, commercial health insurance with prescription coverage for VILTEPSO medication, and your insurance does not cover the entire cost of VILTEPSO.
- You are under age 65.
- There is no income requirement.
- The Program covers only the cost of VILTEPSO and not the cost of any infusion services or healthcare provider visits, which are the sole responsibility of the patient.
- You will be automatically re-enrolled every calendar year as long as you continue to meet the eligibility requirements for participation in the Program.
- You are responsible for reporting receipt of co-pay assistance to any insurer, health plan, or other third party who pays for or reimburses any part of the medication or treatment cost using the NS Support Co-pay Assistance Program, as may be required.
- You must not seek reimbursement, in whole or in part, from government health insurance (eg, Medicare, Medicaid, Indian Health Service, Veterans Administration, Department of Defense, or any other federal or state government assistance programs), a Flexible Spending Account (FSA), a Health Savings Account (HSA), or a Health Reimbursement Account (HRA).
- You will not in any way report or count the value of the product provided under this Program as true out-of-pocket (TrOOP) spending under a Medicare Part D prescription drug benefit.
- Claims must be submitted in a timely manner. An EOB from your private, commercial health insurance must be submitted within 365 days of the date of service on the EOB for you to receive a co-pay assistance benefit. No EOB may be submitted more than 90 days after the expiration date of the NS Support Co-pay Assistance Program, and the date of service on the EOB must be prior to the program expiration date. The EOB must reflect your out-of-pocket cost for VILTEPSO and submission of the claim by your physician for the cost of the medication.
- The NS Support Co-pay Assistance Program is not health insurance.
- NS Pharma, Inc. has the right to modify, alter, or cancel the NS Support Co-pay Assistance Program at any time without prior notification.

INDICATION

VILTEPSO is 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.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions: Kidney toxicity was observed in animals who received viltolarsen. Although kidney toxicity was not observed in the clinical studies with VILTEPSO, the clinical experience with VILTEPSO is limited, and kidney toxicity, including potentially fatal glomerulonephritis, has been observed after administration of some antisense oligonucleotides. Kidney function should be monitored in patients taking VILTEPSO. Serum creatinine may not be a reliable measure of kidney function in DMD patients.

Serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio should be measured before starting VILTEPSO. Consider also measuring glomerular filtration rate before starting VILTEPSO. During treatment, monitor urine dipstick every month, and serum cystatin C and urine protein-to-creatinine ratio every three months.

Urine should be free of excreted VILTEPSO for monitoring of urine protein. Obtain urine either prior to VILTEPSO infusion, or at least 48 hours after the most recent infusion. Alternatively, use a laboratory test that does not use the reagent pyrogallol red, which has the potential to generate a false positive result due to cross reaction with any VILTEPSO in the urine. If a persistent increase in serum cystatin C or proteinuria is detected, refer to a pediatric nephrologist for further evaluation.

Adverse Reactions: The most common adverse reactions include upper respiratory tract infection, injection site reaction, cough, and pyrexia.

To report an adverse event, or for general inquiries, please call NS Pharma Medical Information at 1-866-NSPHARM (1-866-677-4276).

For more information about VILTEPSO, visit www.VILTEPSO.com and see full [Prescribing Information](#).

Connect with NS Support today!



833-NSSUPRT (833-677-8778)
Monday–Friday, 8 AM–8 PM ET

References: 1. Use of average sales price payment methodology. 42 USC § 1395w-3a (2012). Accessed September 14, 2023. <https://www.govinfo.gov/content/pkg/USCODE-2012-title42/pdf/USCODE-2012-title42-chap7-subchapXVIII-partB-sec1395w-3a.pdf> 2. American Medical Association. CPT® 2023 Professional Edition. United States; American Medical Association; 2022. 3. CMS website. Medicare Claims Processing Manual, Chapter 17 - Drugs and Biologicals. Revised December 22, 2022. Accessed September 14, 2023. [cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf) 4. CMS website. Beneficiaries Dually Eligible for Medicare and Medicaid. MLN Fact Sheet. Accessed September 14, 2023. [cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Medicare_Beneficiaries_Dual_Eligibles_At_a_Glance.pdf](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Medicare_Beneficiaries_Dual_Eligibles_At_a_Glance.pdf) 5. CMS website. Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures. Revised April 2022. Accessed September 14, 2023. [cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2018-11-30-HCPCS-Level2-Coding-Procedure.pdf](https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2018-11-30-HCPCS-Level2-Coding-Procedure.pdf) 6. American Health Information Management Association (AHIMA) website. Frequently Asked Questions about ICD-10-CM/PCS. Accessed September 14, 2023. [bok.ahima.org/PdfView?oid=107590](https://www.ahima.org/PdfView?oid=107590) 7. CMS website. Medicare-FFS Program. Billing 340B Modifiers Under the Hospital Outpatient Prospective Payment System (OPPS): Frequently Asked Questions. Accessed September 14, 2023. [cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/billing-340b-modifiers-under-hospital-ops.pdf](https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/billing-340b-modifiers-under-hospital-ops.pdf) 8. BCBS of Texas website. Billing with National Drug Codes (NDCs) Frequently Asked Questions. Accessed September 14, 2023. https://www.bcbsbx.com/docs/provider/bv/claims/claims-filing/drug-and-national-drug-code-ndc-ndc_faqs.pdf 9. Value Healthcare Services website. Understanding hospital revenue codes. Accessed September 14, 2023. valuehealthcareservices.com/education/understanding-hospital-revenue-codes/ 10. CMS website. Medicare Claims Processing Manual, Chapter 12 - Physicians/Nonphysician Practitioners. Revised February 9, 2023. Accessed September 14, 2023. [cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf) 11. VILTEPSO. Prescribing Information. NS Pharma, Inc.; 2021. 12. American Medical Association. ICD-10-CM Expert for Physicians 2023. United States; American Medical Association; 2022. 13. American Medical Association. HCPCS Level II 2023. United States; American Medical Association; 2022. 14. CMS website. CMS HCPCS Application Summaries and Coding Decisions. Fourth Quarter, 2020 Coding Cycle for Drugs and Biologic Products. Accessed September 14, 2023. <https://www.cms.gov/files/document/2020-hcpcs-application-summary-quarter-4-2020-drugs-and-biologics.pdf>



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