NS Support®
NS PHARMA **ACCESS SOLUTIONS**

Resource Guide

Helping with patient access to VILTEPSO® (viltolarsen)

Viltepso®
(viltolarsen) injection

NS Support
NS PHARMA ACCESS SOLUTIONS

Putting your patients and your practice in touch with personalized access support and customized resources from NS Pharma

At NS Support, we are dedicated to being a committed partner to the families coping with Duchenne muscular dystrophy (DMD). We stand ready to provide optimal access support and resources for your patients, those who care for them, and your practice.

When you prescribe VILTEPSO® (viltolarsen), we are uniquely able to identify and tackle the access and affordability challenges that your patients may encounter.

Case Manager

Your personal connection provides ongoing support to help manage and expedite access, reimbursement, and care coordination for patients and those who care for them.

Director of Patient Access

A knowledgeable, experienced professional can visit your office to discuss patient access and affordability resources and provide support to help streamline health plan coverage approvals and appeals.

Patient Engagement Lead

This dedicated resource works directly with patients and caregivers to provide personalized access support, coordinate care, and help reduce delays throughout the treatment journey.

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 no patients experienced kidney toxicity during treatment 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. Because of the effect of reduced skeletal muscle mass on creatinine measurements, 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 and during treatment with VILTEPSO. Consider measuring GFR before starting VILTEPSO.
- **Adverse Reactions:** The most common adverse reactions include upper respiratory tract infection, injection site reaction, cough, and pyrexia.

Support right from the start

*Prior authorization and exceptions and appeals assistance is limited. NS Support does not provide any information that requires the medical judgment of the prescriber and only the prescriber can determine whether to pursue a prior authorization, an exception, or an appeal.

For more information about VILTEPSO, visit www.VILTEPSO.com and see full Prescribing Information.

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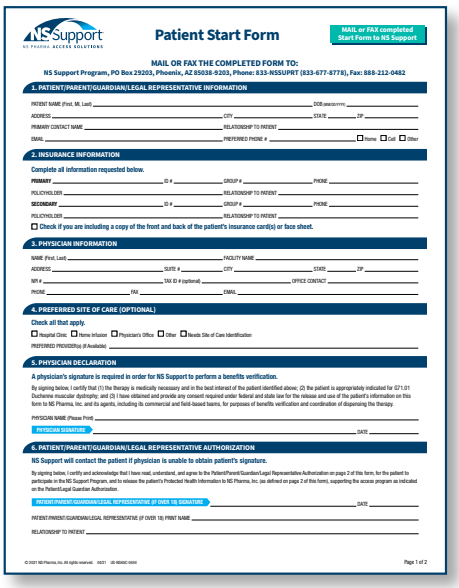
833-NSSUPRT (833-677-8778)
Monday–Friday, 8 AM–8 PM ET

When you start your patient on VILTEPSO® (viltolarsen) ...

Just complete the Patient Start Form and submit to NS Support



NS Support
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Patient Start Form

MAIL or FAX completed Start Form to NS Support

MAIL OR FAX THE COMPLETED FORM TO:
NS Support Program, PO Box 29203, Phoenix, AZ 85038-9203, Phone: 833-NSSUPRT (833-677-8778), Fax: 888-212-0482

1. PATIENT/PARENT/GUARDIAN/LEGAL REPRESENTATIVE INFORMATION

PATIENT NAME (First, MI, Last) _____ DOB (MM/DD/YYYY) _____
ADDRESS _____ CITY _____ STATE _____ ZIP _____
PRIMARY CONTACT NAME _____ RELATIONSHIP TO PATIENT _____
EMAIL _____ PREFERRED PHONE # _____ ☐ Home ☐ Cell ☐ Other

2. INSURANCE INFORMATION

Complete all information requested below.

PRIMARY _____ ID # _____ GROUP # _____ PHONE _____
POLICYHOLDER _____ RELATIONSHIP TO PATIENT _____
SECONDARY _____ ID # _____ GROUP # _____ PHONE _____
POLICYHOLDER _____ RELATIONSHIP TO PATIENT _____
☐ **Check if you are including a copy of the front and back of the patient's insurance card(s) or face sheet.**

3. PHYSICIAN INFORMATION

NAME (First, Last) _____ FACILITY NAME _____
ADDRESS _____ SUITE # _____ CITY _____ STATE _____ ZIP _____
NPI # _____ TAX ID # (optional) _____ OFFICE CONTACT _____
PHONE _____ FAX _____ EMAIL _____

4. PREFERRED SITE OF CARE (OPTIONAL)

Check all that apply.
☐ Hospital Clinic ☐ Home Infusion ☐ Physician's Office ☐ Other ☐ Needs Site of Care Identification
PREFERRED PROVIDER(s) (If Available) _____

5. PHYSICIAN DECLARATION

A physician's signature is required in order for NS Support to perform a benefits verification.

By signing below, I certify that (1) the therapy is medically necessary and in the best interest of the patient identified above; (2) the patient is appropriately indicated for ICD-10 Duchenne muscular dystrophy; and (3) I have obtained and provide any consent required under federal and state law for the release and use of the patient's information on this form to NS Pharma, Inc. and its agents, including its commercial and field-based teams, for purposes of benefits verification and coordination of dispensing the therapy.

PHYSICIAN NAME (Please Print) _____
PHYSICIAN SIGNATURE _____ DATE _____

6. PATIENT/PARENT/GUARDIAN/LEGAL REPRESENTATIVE AUTHORIZATION

NS Support will contact the patient if physician is unable to obtain patient's signature.

By signing below, I certify and acknowledge that I have read, understand, and agree to the Patient/Parent/Guardian/Legal Representative Authorization on page 2 of this form, for the patient to participate in the NS Support Program, and to release the patient's Protected Health Information to NS Pharma, Inc. (as defined on page 2 of this form), supporting the access program as indicated on the Patient/Legal Guardian Authorization.

PATIENT/PARENT/GUARDIAN/LEGAL REPRESENTATIVE (IF OVER 18) SIGNATURE _____ DATE _____
PATIENT/PARENT/GUARDIAN/LEGAL REPRESENTATIVE (IF OVER 18) PRINT NAME _____
RELATIONSHIP TO PATIENT _____

- The completed Patient Start Form automatically activates NS Support*
  - Initiates the benefits investigation process
  - Enrolls your patient in the Co-pay Assistance Program for VILTEPSO

Fax or mail the completed Patient Start Form to NS Support

Fax: 888-212-0482

Mail: NS Support, PO Box 29203, Phoenix, AZ 85038-9203

*NS Support cannot enroll patients in NS Support services without Patient/Parent/Guardian/Legal Representative Authorization, which can be found on the Patient Start Form, or a separate signed Patient Authorization Form for VILTEPSO on file. In addition, an NS Support Patient Start Form must be submitted for each patient for whom treatment with VILTEPSO is requested.

Patient insurance benefits investigation is provided as a service by RxC Acquisition Company d.b.a. RxCrossroads by McKesson under contract for NS Pharma, Inc. RxCrossroads by McKesson provides assistance in determining whether treatment can be covered by the payor based on the payor's health plan guidelines and the patient information you provided as authorized by the patient/parent/guardian/legal representative on the Patient Start Form, following your determination of medical necessity.

Verification of insurance coverage is ultimately the responsibility of the provider. Since reimbursement by payors is subject to many factors, RxCrossroads by McKesson and NS Pharma, Inc. do not represent or guarantee that payor reimbursement or any other payment or reimbursement of any kind will be made. Information provided as a result of the benefits investigation is provided for general reference and informational purposes only. RxCrossroads by McKesson makes every effort to be accurate in the information provided; however, no representations or warranties are expressed or implied by RxCrossroads by McKesson and NS Pharma, Inc. regarding the accuracy or reliability of the information. RxCrossroads by McKesson or NS Pharma, Inc. or its agents or employees shall not be liable legally, financially, or otherwise, for damages of any kind as a result of or related to these services. Providers and other users of this information resulting from benefits investigation services accept full responsibility for use of the service.

NS Pharma, Inc. does not assume responsibility for, nor does it guarantee the availability, scope, or quality of the services offered including reimbursement support, prescription fulfillment coordination, and other services under NS Support. Providers, not NS Pharma, Inc., are responsible for the services they provide. NS Support services have no value apart from the product.

We'll provide support for you ...

- Acknowledge receipt of the completed Patient Start Form within 2 hours
- Verify insurance benefits within 2 business days
  - Advise if a prior authorization (PA) is required
  - Send a concise benefits summary to your office, your patient, and their parents or caregiver
- Provide limited support for PA and exceptions and appeals process
  - Research the patient's health plan for PA requirements and forms
  - Monitor the status of the PA submission
  - Notify your office within 3 weeks prior to PA expiration
  - Proactively support the reauthorization process to help mitigate the potential for treatment interruption
- Support streamlined product acquisition options via:
  - Buy & Bill through our specialty distribution network
  - Specialty pharmacy, including assignment of medical benefits for in-office, hospital outpatient department (HOPD), infusion center, or home infusion provider

... and your patients

An experienced, personally assigned Case Manager is ready to offer your patients and their caregivers individualized, caring support and resources throughout the patient journey.

- Explain insurance benefits and out-of-pocket cost support options
- Provide insights about convenient infusion site options
- Discuss alternative and supplemental sources of financial assistance
- Offer appointment follow-up calls and reminders as needed
- Provide information about national and local advocacy organizations offering support for patients and those who care for them

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Monday–Friday, 8 AM–8 PM ET

Support for submitting the Patient Start Form

A completed Patient Start Form connects your office and your patients with personalized support. Completed forms can be submitted by fax to 888-212-0482, or mailed to NS Support, PO Box 29203, Phoenix, AZ 85038-9203.

Following receipt of a completed Patient Start Form, NS Support will:

- Verify insurance benefits within 2 business days
- Advise if a prior authorization is required
- Provide a benefits summary
- Call the patient to discuss access and out-of-pocket assistance

Ordering VILTEPSO® (viltolarsen)

- Following submission of a Patient Start Form, each patient will be assigned a unique NS Support Patient ID
- You may then use the NS Support Product Order Form along with the Patient ID to place an order from the NS Support specialty distribution network

If acquiring VILTEPSO through a specialty pharmacy, NS Support will coordinate the Assignment of Benefits, order placement, and shipping instructions.

1. Complete the required patient information
2. Provide insurance information or attach a copy of the front and back of the patient's insurance card(s) or face sheet
3. Complete to ensure prompt communication with your office
4. Optional: Indicate preferred site(s) of infusion and facility name(s)
5. Sign here to authorize contact with the patient and initiate the benefits investigation process
6. Ask the patient or parent (or their guardian or legal representative) to read the Patient Authorization information on page 2 of the form and sign or mail the Patient Authorization Form to the patient's home and submit it by mail or fax

Sample form

NS Support
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Patient Start Form

MAIL or FAX completed Start Form to NS Support

MAIL OR FAX THE COMPLETED FORM TO:
NS Support Program, PO Box 29203, Phoenix, AZ 85038-9203, Phone: 833-NSSUPRT (833-677-8778), Fax: 888-212-0482

1. PATIENT/PARENT/GUARDIAN/LEGAL REPRESENTATIVE INFORMATION

PATIENT NAME (First, MI, Last) _____ DOB (MM/DD/YYYY) _____

ADDRESS _____ CITY _____ STATE _____ ZIP _____

PRIMARY CONTACT NAME _____ RELATIONSHIP TO PATIENT _____

EMAIL _____ PREFERRED PHONE # _____ ☐ Home ☐ Cell ☐ Other

2. INSURANCE INFORMATION

Complete all information requested below.

PRIMARY _____ ID # _____ GROUP # _____ PHONE _____

POLICYHOLDER _____ RELATIONSHIP TO PATIENT _____

SECONDARY _____ ID # _____ GROUP # _____ PHONE _____

POLICYHOLDER _____ RELATIONSHIP TO PATIENT _____

☐ **Check if you are including a copy of the front and back of the patient's insurance card(s) or face sheet.**

3. PHYSICIAN INFORMATION

NAME (First, Last) _____ FACILITY NAME _____

ADDRESS _____ SUITE # _____ CITY _____ STATE _____ ZIP _____

NPI # _____ TAX ID # (optional) _____ OFFICE CONTACT _____

PHONE _____ FAX _____ EMAIL _____

4. PREFERRED SITE OF CARE (OPTIONAL)

Check all that apply.

☐ Hospital Clinic ☐ Home Infusion ☐ Physician's Office ☐ Other ☐ Needs Site of Care Identification

PREFERRED PROVIDER(s) (If Available) _____

5. PHYSICIAN DECLARATION

A physician's signature is required in order for NS Support to perform a benefits verification.

By signing below, I certify that (1) the therapy is medically necessary and in the best interest of the patient identified above; (2) the patient is appropriately indicated for G71.01 Duchenne muscular dystrophy; and (3) I have obtained and provide any consent required under federal and state law for the release and use of the patient's information on this form to NS Pharma, Inc. and its agents, including its commercial and field-based teams, for purposes of benefits verification and coordination of dispensing the therapy.

PHYSICIAN NAME (Please Print) _____

PHYSICIAN SIGNATURE _____ DATE _____

6. PATIENT/PARENT/GUARDIAN/LEGAL REPRESENTATIVE AUTHORIZATION

NS Support will contact the patient if physician is unable to obtain patient's signature.

By signing below, I certify and acknowledge that I have read, understand, and agree to the Patient/Parent/Guardian/Legal Representative Authorization on page 2 of this form, for the patient to participate in the NS Support Program, and to release the patient's Protected Health Information to NS Pharma, Inc. (as defined on page 2 of this form), supporting the access program as indicated on the Patient/Legal Guardian Authorization.

PATIENT/PARENT/GUARDIAN/LEGAL REPRESENTATIVE (IF OVER 18) SIGNATURE _____ DATE _____

PATIENT/PARENT/GUARDIAN/LEGAL REPRESENTATIVE (IF OVER 18) PRINT NAME _____

RELATIONSHIP TO PATIENT _____

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Identifying ways to help patients afford their 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.*

Co-pay Assistance Program

ELIGIBLE PATIENTS PAY AS LITTLE AS **$0** FOR VILTEPSO PER INFUSION

Restrictions apply. $20,000 maximum program benefit per calendar year per eligible patient. Program covers the cost of the medication only and does not cover the costs to administer the infusion. See full Eligibility Requirements & Terms and Conditions on page 13 for details.

For your patients:

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

For your office:

- Processes for submitting a request for co-pay assistance by electronic or paper submission
- Call 833-NSSUPRT (833-677-8778) to contact your Director of Patient Access for additional information about the program

* Restrictions apply. $20,000 maximum program benefit per calendar year per eligibility criteria. See full Eligibility Requirements & Terms and Conditions.

The 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.

Simplified co-pay assistance at the time of treatment

A personalized program card will be mailed to patients or their caregivers

Patient ID
Identifies a patient enrolled in NS Support

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

For Infusion Providers

- Use the patient information on the front of the card to prepare the submission of a co-pay assistance request
- Use the information on the back of the card to submit the request to McKesson Corporation:
  - Medical Benefit Claims: Fax to Change Healthcare: 888-654-1121 or use EDI: 837 transaction, Change Healthcare, Payer ID: 26227
  - Pharmacy Benefit Claims questions: Call 800-657-7613
  - For primary commercial prescription insurance, input as secondary coverage and transmit using COB segment of NCPDP transaction

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. Completed forms can be faxed to 888-212-0482, or mailed to: NS Support, PO Box 29203, Phoenix, AZ 85038-9203.

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Additional cost support options

Patients with Medicaid and other government-funded insurance

We can provide information about government-funded insurance, including Social Security Disability Insurance (SSDI) and government health plan options for VILTEPSO® (viltolarsen), including:

- Medicaid
- Children's Health Insurance Plan (CHIP)
- Medicare
- Dual-eligible Special Needs Plans (D-SNPs)

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*
  - Restrictions apply. See full Eligibility Requirements & Terms and Conditions on page 14

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

*Patients, parents, guardians, or legal representatives may be responsible for additional costs associated with administration of the drug.

Ongoing support for your patients

Individualized treatment continuation support

We provide eligible patients with access to medication to help avoid interruption of therapy:

- Treatment continuation during the health plan reauthorization process
- While in transition from commercial insurance to Medicaid and/or Medicare

Insights about treatment and infusion site-of-care options

- Help patients and those who care for them understand the treatment process
- Discuss infusion site-of-care options to help patients and those who care for them determine the best setting for treatment:
  - Physician office
  - Ambulatory infusion center
  - Hospital outpatient departments
  - Home infusion
- Help confirm patient health plan coverage at the site of care
- Provide support for referrals
  - Including coordination with home infusion providers

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Support for your office staff

NS Support offers a range of resources to help you and your office staff navigate the sometimes complex reimbursement process.

Limited exceptions and appeals assistance

If your patient is denied coverage, NS Support provides helpful information regarding the steps typically required to:

- Request coverage under a health plan's exceptions process
- Use the appeals process if an exception request is denied

Coding and billing information

The NS Support Coding and Billing Guide provides:

- General coding and billing information to support claims submissions for VILTEPSO® (viltolarsen)*
  - Sample CMS-1500 and UB-04 claims forms
- Answers to coding- and claims-related questions concerning:
  - General and policy-specific procedures
  - Policies for accurate and complete claims documentation, per payor requirements

Ask your NS Pharma Director of Patient Access for a copy of these resources.

* Each healthcare provider is ultimately responsible for determining the appropriate codes, coverage, and payment for individual patients. NS Support does not guarantee third-party coverage or payment for VILTEPSO or reimburse for denied claims. Providers should contact their third-party payors 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 to 8 PM ET.

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 on December 31 in subsequent calendar years after the initial enrollment period ends 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 spending (TrOOP) 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 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.

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

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 must 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.

Resources to support patient access to treatment

Please use the forms attached, also available at www.VILTEPSO.com

- Patient Start Form
- Patient Authorization Form
- Sample Letter of Medical Necessity (for reference only)
- NS Support Product Order Form

Connect with NS Support today!

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Monday–Friday, 8 AM–8 PM ET

Committed to ongoing access and affordability solutions for patients prescribed VILTEPSO® (viltolarsen) and those who care for them.

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 no patients experienced kidney toxicity during treatment 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. Because of the effect of reduced skeletal muscle mass on creatinine measurements, 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 and during treatment with VILTEPSO. Consider measuring GFR before starting VILTEPSO.
- **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.

We're here to help. Call us today!

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Patient Start Form

MAIL or FAX completed Start Form to NS Support

MAIL OR FAX THE COMPLETED FORM TO:

NS Support Program, PO Box 29203, Phoenix, AZ 85038-9203, Phone: 833-NSSUPRT (833-677-8778), Fax: 888-212-0482

1. PATIENT/PARENT/GUARDIAN/LEGAL REPRESENTATIVE INFORMATION

PATIENT NAME (First, MI, Last) _____ DOB (MM/DD/YYYY) _____

ADDRESS _____ CITY _____ STATE _____ ZIP _____

PRIMARY CONTACT NAME _____ RELATIONSHIP TO PATIENT _____

EMAIL _____ PREFERRED PHONE # _____ ☐ Home ☐ Cell ☐ Other

2. INSURANCE INFORMATION

Complete all information requested below.

PRIMARY _____ ID # _____ GROUP # _____ PHONE _____

POLICYHOLDER _____ RELATIONSHIP TO PATIENT _____

SECONDARY _____ ID # _____ GROUP # _____ PHONE _____

POLICYHOLDER _____ RELATIONSHIP TO PATIENT _____

☐ **Check if you are including a copy of the front and back of the patient's insurance card(s) or face sheet.**

3. PHYSICIAN INFORMATION

NAME (First, Last) _____ FACILITY NAME _____

ADDRESS _____ SUITE # _____ CITY _____ STATE _____ ZIP _____

NPI # _____ TAX ID # (optional) _____ OFFICE CONTACT _____

PHONE _____ FAX _____ EMAIL _____

4. PREFERRED SITE OF CARE (OPTIONAL)

Check all that apply.

☐ Hospital Clinic ☐ Home Infusion ☐ Physician's Office ☐ Other ☐ Needs Site of Care Identification

PREFERRED PROVIDER(s) (If Available) _____

5. PHYSICIAN DECLARATION

A physician's signature is required in order for NS Support to perform a benefits verification.

By signing below, I certify that (1) the therapy is medically necessary and in the best interest of the patient identified above; (2) the patient is appropriately indicated for G71.01 Duchenne muscular dystrophy; and (3) I have obtained and provide any consent required under federal and state law for the release and use of the patient's information on this form to NS Pharma, Inc. and its agents, including its commercial and field-based teams, for purposes of benefits verification and coordination of dispensing the therapy.

PHYSICIAN NAME (Please Print) _____

PHYSICIAN SIGNATURE _____ DATE _____

6. PATIENT/PARENT/GUARDIAN/LEGAL REPRESENTATIVE AUTHORIZATION

NS Support will contact the patient if physician is unable to obtain patient's signature.

By signing below, I certify and acknowledge that I have read, understand, and agree to the Patient/Parent/Guardian/Legal Representative Authorization on page 2 of this form, for the patient to participate in the NS Support Program, and to release the patient's Protected Health Information to NS Pharma, Inc. (as defined on page 2 of this form), supporting the access program as indicated on the Patient/Legal Guardian Authorization.

PATIENT/PARENT/GUARDIAN/LEGAL REPRESENTATIVE (IF OVER 18) SIGNATURE _____ DATE _____

PATIENT/PARENT/GUARDIAN/LEGAL REPRESENTATIVE (IF OVER 18) PRINT NAME _____

RELATIONSHIP TO PATIENT _____

Clear Form Print Form

Patient/Parent/Guardian/Legal Representative Copy

Provider Instructions – NS Support will contact the patient if the physician is unable to obtain patient's signature.

1. **Instruct the patient or parent/guardian/legal representative to read this page and sign the authorization in Section 6 on page 1 of the Patient Start Form.**
2. **Give the patient or parent/guardian/legal representative a copy of page 1 of the Patient Start Form, and a copy of the Parent/Guardian/Legal Representative Authorization on this page.**

PARENT/GUARDIAN/LEGAL REPRESENTATIVE AUTHORIZATION ON BEHALF OF PATIENT

Permission to share and use your Protected Health Information

My (or my parent/guardian/legal representative's) signature on page 1 of the Patient Start Form ("the Form") authorizes each of my physicians and pharmacists (including any specialty pharmacies and other healthcare providers) and each of my health insurers to use and disclose my Protected Health Information ("PHI"), including but not limited to medical records, information related to my medical condition and treatment, financial information, lab values, insurance coverage information, my name, address, and telephone number, to NS Pharma, Inc., and its agents, contractors, and assignees (together, "NS Pharma") to enroll me in and contact me (or my parent/guardian/legal representative) about NS Support, provide case management through telephone or electronic communications to assist with adherence to my medication regimen, and work with third parties to provide community resources and referrals. Third-party vendors, such as specialty pharmacies, may receive financial renumeration in exchange for data, product support services, reimbursement services, etc. This authorization expires 5 years from the date of execution, or 1 year after the date of my last prescription, whichever is later, unless a shorter period is required by state law. I (or my parent/guardian/legal representative) understand that I (or my parent/guardian/legal representative) may refuse to sign this authorization and that my treatment, payment, enrollment, or eligibility for benefits, including my access to therapy, is not conditioned on signing this authorization. I (or my parent/guardian/legal representative) understand that revoking this authorization will not affect the ability to use and disclose PHI received prior to receipt of notification that I (or my parent/guardian/legal representative) wish to discontinue my participation in the program. I (or my parent/guardian/legal representative) understand that I (or my parent/guardian/legal representative) may revoke this authorization at any time verbally at 833-NSSUPRT (833-677-8778) or in writing to NS Support at PO Box 29203, Phoenix, AZ 85038-9203. Once authorization has been revoked or expired, I (or my parent/guardian/legal representative) understand that my future PHI will not be disclosed. I (or my parent/guardian/legal representative) understand that my PHI will not be used or disclosed for any other purposes, unless permitted by law, than for the purposes stated above. Information disclosed pursuant to this authorization or provided to a third-party may no longer be protected by federal privacy laws. I (or my parent/guardian/legal representative) understand that I (or my parent/guardian/legal representative) have a right to receive a copy of this authorization.

Cancelling this authorization

A copy of this authorization will be as valid as the original. Cancelling this authorization will not affect the ability of NS Pharma to use and disclose Protected Health Information that it has received prior to receipt of the cancellation of my (or my parent/guardian/legal representative's) authorization. My (or my parent/guardian/legal representative's) authorization will also end if NS Support is discontinued. Furthermore, I (or my parent/guardian/legal representative) understand that I (or my parent/guardian/legal representative) have the right to see or copy the Protected Health Information the patient's Healthcare Providers or Insurers have given to NS Pharma.

Mail or fax (do not email) the completed form to:
NS Support Program, PO Box 29203, Phoenix, AZ 85038-9203, Fax: 888-212-0482

Call NS Support at

NS Support® NS PHARMA ACCESS SOLUTIONS

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

NS Pharma

Patient Authorization Form for VILTEPSO® (viltolarsen)

NS Support
NS PHARMA ACCESS SOLUTIONS

MAIL OR FAX THE SIGNED FORM TO:

NS Support, PO Box 29203, Phoenix, AZ 85038-9203, Phone: 833-NSSUPRT (833-677-8778), Fax: 888-212-0482

Provider Instructions

1. **Instruct the patient or parent/guardian/legal representative to read this page and sign the authorization.**
2. **Give the patient or parent/guardian/legal representative a copy of this page.**

PATIENT/PARENT/GUARDIAN/LEGAL REPRESENTATIVE AUTHORIZATION ON BEHALF OF PATIENT

Permission to share and use Protected Health Information

My (or my parent/guardian/legal representative's) signature below authorizes each of my physicians and pharmacists (including any specialty pharmacies and other healthcare providers) and each of my health insurers to use and disclose my Protected Health Information ("PHI"), including but not limited to medical records, information related to my medical condition and treatment, financial information, lab values, insurance coverage information, my name, address, and telephone number, to NS Pharma, Inc., and its agents, contractors, and assignees (together, "NS Pharma") to enroll me in and contact me (or my parent/guardian/legal representative) about NS Support, provide case management through telephone or electronic communications to assist with adherence to my medication regimen, and work with third parties to provide community resources and referrals. Third-party vendors, such as specialty pharmacies, may receive financial renumeration in exchange for data, product support services, reimbursement services, etc. This authorization expires 5 years from the date of execution, or 1 year after the date of my last prescription, whichever is later, unless a shorter period is required by state law. I (or my parent/guardian/legal representative) understand that I (or my parent/guardian/legal representative) may refuse to sign this authorization and that my treatment, payment, enrollment, or eligibility for benefits, including my access to therapy, is not conditioned on signing this authorization. I (or my parent/guardian/legal representative) understand that revoking this authorization will not affect the ability to use and disclose PHI received prior to receipt of notification that I (or my parent/guardian/legal representative) wish to discontinue my participation in the program. I (or my parent/guardian/legal representative) understand that I (or my parent/guardian/legal representative) may revoke this authorization at any time verbally at 833-NSSUPRT (833-677-8778) or in writing to NS Support at PO Box 29203, Phoenix, AZ 85038-9203. Once authorization has been revoked or expired, I (or my parent/guardian/legal representative) understand that my future PHI will not be disclosed. I (or my parent/guardian/legal representative) understand that my PHI will not be used or disclosed for any other purposes, unless permitted by law, than for the purposes stated above. Information disclosed pursuant to this authorization or provided to a third-party may no longer be protected by federal privacy laws. I (or my parent/guardian/legal representative) understand that I (or my parent/guardian/legal representative) have a right to receive a copy of this authorization.

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PATIENT/PARENT/GUARDIAN/LEGAL REPRESENTATIVE AUTHORIZATION

By signing below, I certify and acknowledge that I have read, understand, and agree to the Patient/Parent/Guardian/Legal Representative Authorization above, for the patient to participate in the NS Support Program, and to release the patient's Protected Health Information to NS Pharma, Inc., supporting the access program as indicated on this form.

PATIENT NAME _____ DOB (MM/DD/YYYY) _____

PARENT/GUARDIAN/LEGAL REPRESENTATIVE/PATIENT (IF OVER 18) SIGNATURE _____ DATE _____

PARENT/GUARDIAN/LEGAL REPRESENTATIVE/PATIENT (IF OVER 18) PRINT NAME _____

RELATIONSHIP TO PATIENT _____

Clear Form Print Form

NS Pharma

Sample Letter of Medical Necessity

[Insert physician letterhead]

ATTN: MEDICAL DIRECTOR _____ RE: PATIENT NAME _____

INSURANCE COMPANY _____ POLICY # _____ CLAIM # _____

ADDRESS _____ CITY _____ STATE _____ ZIP _____

Dear **[insert name]**:

I am writing to provide additional information to support my claim for the treatment of **[patient name]** with VILTEPSO® (viltolarsen). VILTEPSO 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.

So that I can provide appropriate care for my patient, it is important that **[plan name]** provide coverage for this treatment. This letter provides a summary of **[patient name]**'s medical history, prognosis, and treatment rationale.

SUMMARY OF PATIENT'S HISTORY

Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition. You may want to include:

- Patient's diagnosis, date of diagnosis, method of diagnosis, and diagnosis history, including physical motor function test results (if available).
- Patient's previous and/or current therapies used for the symptoms associated with DMD and responses to these therapies.
- Brief description of the patient's recent symptoms and conditions, including current motor function.
- Summary of your professional opinion of the patient's prognosis and need for VILTEPSO.

RATIONALE FOR TREATMENT

This section should include your clinical rationale and reasons for urgency for the patient's treatment with VILTEPSO. You may consider the following:

- DMD is caused by mutations in the DMD gene on the X chromosome that results in little or no production of dystrophin, a protein that supports muscle health. Exon skipping is a treatment strategy in which sections of genetic code are "skipped" (spliced out or left out) during the protein manufacturing process. This treatment strategy allows cells to create a shortened dystrophin protein that contains essential functional portions.
- VILTEPSO is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 53 skipping. Exon 53 skipping is intended to allow for production of an internally truncated dystrophin protein in patients with genetic mutations that are amenable to exon 53 skipping. The FDA-approved VILTEPSO is for the treatment of 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. The FDA-approved label should be the primary basis for the criteria used to determine insurance coverage.
- In patients (N=8) who received VILTEPSO 80 mg/kg once weekly, mean dystrophin levels increased from 0.6% (SD 0.8) of normal at baseline to 5.9% (SD 4.5) of normal by Week 25.

ADDITIONAL DOCUMENTATION

Provide materials and information that may be requested by Payors in connection with the Letter of Medical Necessity, including chart notes, genetic tests, FDA approval letter, VILTEPSO Prescribing Information, recent medical articles, and information to educate the Medical Director or Pharmacy Director who may not be familiar with DMD or its treatment.

Please call my office at **[phone number]** if I can provide you with any additional information. I look forward to receiving your timely response and approval of this request.

Sincerely,

[Healthcare provider name & participating provider number]

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 no patients experienced kidney toxicity during treatment 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. Because of the effect of reduced skeletal muscle mass on creatinine measurements, 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 and during treatment with VILTEPSO. Consider measuring GFR before starting VILTEPSO.
- **Adverse Reactions:** The most common adverse reactions include upper respiratory tract infection, injection site reaction, cough, and pyrexia.

For more information about VILTEPSO, see full Prescribing Information.

NS Support Product Order Form

Use this Order Form to order/reorder VILTEPSO® (viltolarsen). Fax this completed form to 888-212-0482 or mail to NS Support, PO Box 29203, Phoenix, AZ 85038-9203. For assistance or additional information, call 833-NSSUPRT (833-677-8778), Monday–Friday, 8 AM to 8 PM ET.

PRODUCT ACQUISITION INFORMATION (Required, unless indicated otherwise)

PREFERRED SPECIALTY DISTRIBUTOR

☐ ASD Healthcare ☐ Besse Medical ☐ Cardinal PR ☐ Cardinal SPD ☐ McKesson Plasma & Biologics ☐ McKesson Specialty Care ☐ Metro Medical ☐ Oncology Supply

ACCOUNT # _____ PURCHASE ORDER # (if needed) _____

ACCOUNT TYPE ☐ Provider Office ☐ 340B ☐ PHS ☐ Home Health ☐ Freestanding/Hospital Infusion Center ☐ Other (clinic)

CONTACT NAME _____

PHONE _____ FAX _____ EMAIL _____

NOTE: Provider will be invoiced for VILTEPSO purchased from the specialty distributor at the contracted rates under the provider's agreement or rates quoted at the point-of-sale. Provider is financially responsible for and agrees to pay the distributor all invoiced charges for products ordered by the provider. Each invoice will be due and payable by the provider within the payment terms offered by the distributor on the date of order.

ORDER INFORMATION (Required) – Please fill out section below if your order is for one or more patients with an NS Support Patient ID under the same account.

NS SUPPORT PATIENT ID (existing patients only)	QUANTITY

HEALTHCARE PROVIDER INFORMATION (Required when the healthcare provider is the shipment recipient)

HEALTHCARE PROVIDER NAME (First, Last) _____

ADDRESS _____ SUITE # _____ CITY _____ STATE _____ ZIP _____

PHONE _____ NPI # _____

SHIPPING INFORMATION FOR VILTEPSO (Required)

SHIP TO: ☐ Healthcare Provider's Address ☐ Other

FACILITY NAME _____ HIN # _____

ADDRESS _____ SUITE # _____ CITY _____ STATE _____ ZIP _____

USE OF PRODUCT ACQUISITION INFORMATION

By providing your information and information about your patient on this Order Form, you are placing an order for VILTEPSO to dispense to patients who have been prescribed VILTEPSO. The information you provide will only be used by NS Pharma, Inc., its affiliated companies, agents, and representatives, including providers of alternate sources of funding for prescription drug costs, and other service providers involved in managing and delivering this service for healthcare providers and patients (collectively, "NS Pharma"). You may withdraw your request for this service at any time by calling 833-NSSUPRT (833-677-8778). You agree to be contacted by NS Pharma, Inc. at NS Support by mail, fax, email, or phone for the purposes of managing and delivering this product. Our Privacy Policy, available at https://www.nspharma.com/privacy-policy, governs the use of the information you provide. By providing the information on this Order Form and submitting this Order Form, you indicate that you have read, understand, and agree to these terms and agree to receive program-related communications from NS Support and its service providers. Please call NS Support at 833-NSSUPRT (833-677-8778) if you wish to change your communication preferences. This form is submitted in full compliance with all applicable laws, regulations and rules.

Clear Form Print Form