



Helping to provide affordable access to VILTEPSO® (viltolarsen) injection

Options to make treatment more affordable



Once patients enroll in NS Support, a personally assigned Case Manager can help them and their families identify potential options to make treatment more affordable.

Throughout the patient journey, a dedicated Patient Engagement Lead is available to patients and caregivers to provide personalized access support, coordinate care, and help reduce treatment delays.



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.

NS Support Co-pay Assistance Program

Eligible patients with commercial insurance coverage for treatment with VILTEPSO® (viltolarsen) **may be automatically enrolled** once NS Support receives their completed [Patient Start Form](#) for VILTEPSO.*

For your patients:

- Savings on their co-pay costs for VILTEPSO
- Pay as little as \$0 per infusion (program covers the cost of the medication and does not cover the costs to administer the infusion)
- Applicable out-of-pocket costs are covered—up to \$20,000 per calendar year
- Automatic re-enrollment after 12 months, available **ONLY** to eligible patients with commercial insurance



Patient: Present this card to your infusion provider. By using this card, you certify that you understand the program rules, regulations, eligibility requirements, and terms and conditions, including, but not limited to: you are covered by commercial insurance; you reside and receive treatment in the US or its territories; you are not enrolled in government-funded health coverage (eg, Medicare, Medicaid, Indian Health Service, Department of Defense, or any other federal or state government assistance program). The Program covers the cost of the medication only and does not cover the costs to administer the infusion or any other products or services. See full Eligibility Requirements & Terms and Conditions in the Co-pay Assistance Program brochure.

Infusion provider: By using this card, you certify that you will not submit a claim for reimbursement under any government-funded programs for this prescription.

Submit to McKesson Corporation using information on front of card:

- Medical Benefit Claims: Fax to **888-654-1121**
- 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

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

NS Pharma, Inc. reserves the right to rescind, revoke, or amend this offer at any time.

© 2021 NS Pharma, Inc. All rights reserved. US-NS65C-0647

 NS Pharma

For your office:

- Electronic or paper processes to submit requests for co-pay assistance
- Support with information and answers to questions about the program by calling 833-NSSUPRT (833-677-8778)

*Restrictions apply. See full [Eligibility Requirements & Terms and Conditions](#).

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 12 months 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.



Medicaid Waiver Programs for children with Duchenne muscular dystrophy (DMD)

How Medicaid waivers work

Through the use of Medicaid waivers, a child with DMD and their family may qualify for Medicaid assistance that is not based on income alone. Medicaid waivers may provide these children with additional services and wrap-around Medicaid coverage to help pay for uncovered services.

Because Medicaid waiver programs are state based, they each have their own rules and benefits. Waiver services in one state will not be transferred to other states in the event you move your residence. In addition, many states have people already on waiver waiting lists that are more than 3 years long before services are granted.

Types of Medicaid waivers

1915(c) waivers, more commonly known as Home- and Community-Based Services (HCBS) waivers

- Permit children with medical, developmental, and intellectual disabilities, including those with DMD, who are not low income to access Medicaid
- Provide services beyond regular Medicaid so that children with DMD can be treated in home- or community-based settings, rather than in long-term care facilities, such as nursing homes
- All states have some type of HCBS waiver program, and most states have more than one HCBS program

Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA)/Katie Beckett waivers

- Provide full or additional coverage, including the cost of medications, for children younger than 19 who live at home with physical or mental disabilities, mental illness, or other complex medical needs
- Financial eligibility for a child with DMD is based only on the child's income and assets, and not on the income of his parents
- States that offer TEFRA/Katie Beckett waivers must serve all eligible children who apply, and there is no waiting list
- However, TEFRA/Katie Beckett programs are voluntary, meaning states can choose whether or not to offer them

Section 1115 waivers

- Present an opportunity for states to create unique programs to meet the needs of children with disabilities or replace their Medicaid program entirely:
 - Expand eligibility to individuals who are not otherwise Medicaid or CHIP eligible
 - Provide services not typically covered by Medicaid
 - Use innovative service delivery systems that improve care, increase efficiency, and reduce costs as long as these systems do not increase federal Medicaid expenditures

To learn more about Medicaid waivers available in your state, visit: [medicaidwaiver.org](https://www.medicaidwaiver.org) and click on “Disability Benefits.”

[Kidswaivers.org](https://www.kidswaivers.org) is another helpful resource for learning more about Medicaid waivers for children.

Patient Assistance Program (PAP) for VILTEPSO

- May help patients in financial need who are uninsured.
- Patients who meet program requirements may be able to receive VILTEPSO at no charge for up to one year (program covers the cost of the medication and does not cover the costs to administer the infusion).
- Restrictions apply. See full Eligibility Requirements & Terms and Conditions below.

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.



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



NS Pharma and the symbol for NS Pharma are registered trademarks of Nippon Shinyaku Co., Ltd.

VILTEPSO is a registered trademark of Nippon Shinyaku Co., Ltd.

The NS Support logo is a registered trademark of NS Pharma, Inc.

For US audiences only.

© 2021 NS Pharma, Inc. All rights reserved. 10/21 US-NS65C-0785



NS PHARMA ACCESS SOLUTIONS

833-NSSUPRT (833-677-8778)

Patient Start Form

FAX OR MAIL THE COMPLETED FORM TO NS SUPPORT

888-212-0482

PO Box 7613, Overland Park, KS 66207-9941

PLEASE COMPLETE ALL SECTIONS. By providing full information and signatures, you can help avoid processing delays.

1. PATIENT/PARENT/GUARDIAN/LEGAL REPRESENTATIVE INFORMATION

PATIENT FIRST NAME _____ PATIENT LAST NAME _____ DOB (MM/DD/YYYY) _____
ADDRESS _____ CITY _____ STATE _____ ZIP _____
PRIMARY CONTACT NAME _____ RELATIONSHIP TO PATIENT _____
PREFERRED PHONE _____ Home Cell Other PREFERRED LANGUAGE English Spanish
EMAIL _____

2. INSURANCE INFORMATION

Complete all information requested below.

PRIMARY _____ ID # _____ GROUP # _____ PHONE _____
POLICYHOLDER _____ RELATIONSHIP TO PATIENT _____

If you have secondary insurance, such as Medicaid, include it here.

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

PHYSICIAN FIRST NAME _____ PHYSICIAN LAST NAME _____
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. EXON CONFIRMATION

Exon 53 Amenable

6. 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 provided 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, contractors, and assignees, including but not limited to commercial and field-based teams (together, "NS Pharma"), for purposes of benefits verification and coordination of dispensing the therapy. I also certify that I may be contacted by NS Pharma by fax, email, phone calls, and detailed voice messages.

PHYSICIAN NAME (Please Print) _____

PHYSICIAN SIGNATURE

DATE _____

7. PATIENT/PARENT/GUARDIAN/LEGAL REPRESENTATIVE AUTHORIZATION

NS Support will contact the patient if the physician is unable to obtain the 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/Parent/Guardian/Legal Representative Authorization.

Promotional/educational communications consent: Yes, NS Pharma may send me promotional and/or educational patient communications related to my treatment and condition. Examples of these communications may include but are not limited to product information, newsletters, announcements, healthcare reminders, and tips. I understand that I (or my parent/guardian/legal representative) may opt out of receiving these communications at any time by following the instructions on the communications.

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

DATE _____

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

RELATIONSHIP TO PATIENT _____

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



Patient/Parent/Guardian/Legal Representative Copy

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

- 1. Instruct the patient or parent/guardian/legal representative to read this page and sign the authorization in Section 7 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 Patient Engagement Leads, 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 by mail, email, phone calls, detailed voice messages, interactive voice recordings that may include use of auto-dialers or artificial or prerecorded voice messages, and SMS text messages (data rates may apply) as explained in the Telephone Consumer Protection Act (TCPA) consent 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 remuneration in exchange for data, product support services, reimbursement services, etc. This authorization expires 5 years from the date of execution, 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 7613, Overland Park, KS 66207-9941. 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.

Communications consent

By checking the box in Section 7 on page 1 of the Patient Start Form, I authorize NS Pharma to send promotional and/or educational patient communications related to my condition, treatment, or related products or services that might be of interest; to contact me (or my parent/guardian/legal representative) occasionally to obtain feedback for market research purposes about my treatment, condition, or experience with the product, NS Pharma, and/or NS Support; and to contact me (or my parent/guardian/legal representative) about other products and services offered by NS Pharma.

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