

Follow this payer-specific
guide to help maintain
coverage for patients on



REAUTHORIZATION CHECKLISTS



Instructions for Using This Reauthorization Guide

This guide is designed to help you submit a complete and accurate reauthorization request for VILTEPSO® (viltolarsen) based on your patient's health plan requirements. Follow the steps below to navigate the guide and complete the checklist for your patient's payer.

1 SELECT THE PATIENT'S PAYER

- Click the payer logo in the Table of Contents to jump directly to that payer's checklist
- If printing the guide, use the Table of Contents to locate the correct section

2 REVIEW AND COMPLETE EACH CHECKLIST ITEM

Each payer section includes specific clinical and documentation requirements needed for reauthorization. Use the checkboxes provided to ensure that every required item is included in your submission.

3 GATHER ALL SUPPORTING DOCUMENTATION

Attach all medical records, chart notes, genetic test results, assessment scores, and any required prior authorization forms referenced in the checklist. Confirm all relevant elements are addressed. You may be required to submit a letter of medical necessity as part of the reauthorization process. Please refer to your Director of Patient Access (DPA) for available templates and guidance.

4 SUBMIT MATERIALS ACCORDING TO PAYER INSTRUCTIONS

Follow your payer's established submission process (eg, fax, portal upload, EHR-integrated prior authorization tools). A link to the VILTEPSO prescription form is available at the bottom of each page and is required for reauthorization submission. Instructions for completing the prescription form can be accessed [via this link](#).

IMPORTANT NOTES

- Information in this guide reflects the most current publicly available payer criteria at the time of publication, but policies may change at any time
- While many reauthorization criteria remain stable year over year, please always verify requirements directly with the patient's health plan before submitting
- This guide is provided as a resource to support your internal processes; it does not replace payer policy documentation or clinical judgment

Indication

VILTEPSO® (viltolarsen) 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.

Please see full [Important Safety Information](#) and full [Prescribing Information](#).



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



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Checklist for Continuation of Treatment With VILTEPSO® (viltolarsen)



Based on Aetna's Medical Clinical Policy Bulletin;
effective: December 2, 2016; last review: February 13, 2026



ATTESTATION OF MEDICAL NECESSITY

Aetna considers VILTEPSO medically necessary for members requesting continuation of therapy when all of the following criteria are met.



Place a checkmark with the completion of each criterion.



CLINICAL RECORDS AND AMBULATION



Provide documentation of the diagnosis of DMD via genetic testing.



Provide documentation that the DMD gene mutation is amenable to exon 53 skipping.

- Include genetic testing results for both



Provide confirmation that the patient receiving treatment with VILTEPSO is younger than 10 years of age.

NOTE: If the patient is 10 years of age or older, you might consider using the letter of medical necessity directed to addressing treatment of older patients with VILTEPSO.



Provide documents that demonstrate a response to therapy as evidenced by remaining ambulatory (eg, not wheelchair dependent).

- Include test results from recent motor function tests or other documentation

NOTE: If the patient is unable to walk unassisted or is unable to complete the motor function tests, you might consider using the letter of medical necessity directed to addressing treatment of non-ambulatory patients with VILTEPSO.



PRESCRIPTION

Please confirm that:



VILTEPSO is being prescribed by, or in consultation with, a physician who specializes in the treatment of DMD.



The patient will not exceed a dose of 80 mg/kg of VILTEPSO.



VILTEPSO will not be used concomitantly with golodirsen (Vyondys 53®).



The patient has not previously received gene replacement therapy for DMD (eg, Elevidys® [delandistrogene moxeparvovec-rokl]) or has previously received gene replacement therapy for DMD (eg, Elevidys) and has experienced a worsening in clinical status since receiving gene replacement therapy (eg, decline in ambulatory function).

[Fill a VILTEPSO prescription using our form >](#)

Checklist for Continuation of Treatment With VILTEPSO® (viltolarsen)

Based on Anthem/BCBS's Medical Drug Clinical Criteria;
last review: August 15, 2025



COVERAGE: 6 MONTHS

Continuation of therapy with VILTEPSO may be approved if the following criteria are met.



Place a checkmark with the completion of each criterion.



DIAGNOSIS AND CLINICAL RECORDS



Provide documentation that the patient has a confirmed diagnosis of Duchenne muscular dystrophy (DMD).



Provide documentation that the patient has a genetic mutation that is amenable to exon 53 skipping.

- Include genetic test results for both



Provide confirmation that the patient is age 4-9 years.

NOTE: If the patient is younger than 4 years of age or older than 9 years of age, you might consider using the letter of medical necessity directed to addressing treatment with VILTEPSO of either younger or older patients.



Provide documentation that the patient is using a corticosteroid.



Provide documentation that the patient is ambulatory.



Provide motor function test results that the patient can complete the following assessments:

A. Time to stand from supine

B. Time to run/walk 10 meters

C. Time to climb 4 stairs

NOTE: If the patient is unable to walk unassisted or is unable to complete the motor function tests, you might consider using the letter of medical necessity directed to addressing treatment of non-ambulatory patients with VILTEPSO.



Provide documentation that the individual remains ambulatory (with or without assistive device, including but not limited to a cane or walker).

Please confirm that:



The patient will not use VILTEPSO with any other exon-skipping agents for DMD (including but not limited to Exondys 51® [eteplirsen], Vyondys 53® [golodirsen]).

[Fill a VILTEPSO prescription using our form >](#)

Checklist for Continuation of Treatment With VILTEPSO® (viltolarsen)

Based on CareFirst's Prior Authorization Form for VILTEPSO;
last review: October 2022



1. What is the diagnosis?	☒ Duchenne muscular dystrophy (DMD)	☐ Other
2. What is the ICD-10 code?	_____	
3. Is the requested drug prescribed by or in consultation with a physician who specializes in the treatment of DMD?	☒ Yes	☐ No
4. Will the requested medication be used concomitantly with Vyondys 53® (golodirsen)?	☒ Yes	☐ No
5. What is the patient's weight in kilograms?	_____ kg	
6. Does the patient's dose exceed 80 mg/kg once weekly?	☒ Yes	☐ No
7. Is this a request for continuation of therapy with the requested drug? Action: If No, skip to #9.	☒ Yes	☐ No (See Action)
8. Has the patient demonstrated a response to therapy as evidenced by remaining ambulatory (eg, not wheelchair dependent)? Action required. If Yes, attach documentation (eg, chart notes) of response to therapy. If No, then no further questions.	☒ Yes	☐ No (See Action Required)
9. Was genetic testing conducted to confirm the diagnosis of DMD?	☒ Yes	☐ No
10. Was genetic testing conducted to identify the specific type of DMD gene mutation? Action required. If Yes, attach a copy of the genetic testing results.	☒ Yes	☐ No (See Action Required)
11. Please indicate the DMD gene mutation.	_____	
12. Is the DMD gene mutation amenable to exon 53 skipping?	☒ Yes	☐ No
13. Is the patient able to walk independently without assistive devices?	☒ Yes	☐ No
14. Will treatment with the requested drug be initiated prior to age 10?	☒ Yes	☐ No

Checklist for Continuation of Treatment With VILTEPSO® (viltolarsen)

CENTENE®
Corporation

Based on the Clinical Benefit Policy for Centene/Centene Managed Medicaid; effective: August 12, 2020; last review: February 2026



COVERAGE: 6 MONTHS

VILTEPSO may be medically necessary* when the criteria below are met.



Place a checkmark with the completion of each criterion.

*VILTEPSO was FDA approved based on an observed increase in dystrophin in skeletal muscle, but it is unknown if that increase is clinically significant. Continued FDA approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.



CLINICAL RECORDS

Please confirm that:

- ☐ The patient is receiving VILTEPSO for Duchenne muscular dystrophy (DMD) with mutation amenable to exon 53 skipping or has previously met initial approval criteria.
- ☐ Provide documentation that the patient is responding positively to therapy as evidenced by one of the following (A or B):
 - A. ALL** of the following assessed within the last 6 months:
 - Ambulatory function (eg, ability to walk with or without assistive devices, not wheelchair dependent) with one of the following:
 - 1.** 6-Minute Walk Test (6MWT) distance of ≥ 201 meters
 - 2.** Time to Stand (TTSTAND) of < 10 seconds
 - Stable cardiac function with left ventricular ejection fraction (LVEF) $P \geq 40\%$
 - Stable pulmonary function with predicted forced vital capacity (FVC) $\geq 50\%$
 - B.** The patient has received VILTEPSO via a healthcare insurer without meeting the requirements above (criterion A), and the medical record shows improved or stable LVEF and FVC, assessed within the last 6 months
- ☐ The patient has been assessed by a neurologist within the last 6 months.



PRESCRIPTION

Please confirm that:

- ☐ VILTEPSO is prescribed concurrently with an oral corticosteroid, unless contraindicated or clinically significant adverse effects are experienced.
- ☐ VILTEPSO is not prescribed concurrently with other exon-skipping therapies (eg, Amondys 45® [casimersen], Exondys 51® [eteplirsen], Vyondys 53® [golodirsen]).
- ☐ Patient has not previously received gene replacement therapy for DMD (eg, Elevidys® [delandistrogene moxeparvovec-rokl]).
- ☐ The dose of VILTEPSO prescribed does not exceed 80 mg/kg per week.

Fill a VILTEPSO prescription using our form >

Checklist for Continuation of Treatment With VILTEPSO® (viltolarsen)

Based on Cigna's Drug and Biologic Coverage Policy;
effective: October 15, 2025



COVERAGE: 6 MONTHS



Cigna considers VILTEPSO medically necessary for members requesting continuation of therapy when initial criteria are met, individual is able to walk, and there is documentation of beneficial response.



Place a checkmark with the completion of each criterion.



CRITERIA FOR INITIATION OF THERAPY WERE MET



Individual meets ALL of the following criteria (A, B, C, D, and E):

- A.** Documented diagnosis of Duchenne muscular dystrophy (DMD)
- B.** Confirmed mutation of the DMD gene that is amenable to exon 53 skipping
- C.** Younger than 10 years of age at start of therapy
- D.** Able to walk AND must submit baseline 6-Minute Walk Test (6MWT) results
- E.** Medication is being prescribed by, or in consultation with, a neurologist, neuromuscular specialist, or by a Muscular Dystrophy Association (MDA) clinic

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.



CLINICAL RESULTS



Provide documentation of beneficial response, including the continued ability to walk.



Provide recent function test results.

NOTE: If the patient is unable to walk unassisted or is unable to complete the motor function tests, you might consider using the letter of medical necessity directed to addressing treatment of non-ambulatory patients with VILTEPSO.



Results and clinical affirmation as to the continued benefit of treatment with VILTEPSO.

Checklist for Continuation of Treatment With VILTEPSO® (viltolarsen)



Based on Pharmacy Management Drug Policy for Excellus BCBS;
effective: December 20, 2019; last review: November 20, 2025



COVERAGE RATIONALE

Continued approval in non-new starts for additional 6-month periods requires recent documentation of the following criteria.



Place a checkmark with the completion of each criterion.



CLINICAL RECORDS

Recent medical records, including progress notes/test results dated after the most recent drug approval and within 3 months of the continuation period that is being requested, must be submitted to the following:

- ☐ Patient continues to be ambulatory with an unassisted 6-Minute Walk Test (6MWT) of at least 100 meters.
- ☐ Patient has stable cardiac function with left ventricular ejection fraction (LVEF) of >40%.
- ☐ Patient has stable pulmonary function with forced vital capacity $\geq 50\%$ of predicted and does not require supplemental oxygen.
- ☐ <5% annual decline in percent predicted forced vital capacity (FVC% p).

Checklist for Continuation of Treatment With VILTEPSO® (viltolarsen)

Based on Horizon NJ Health's Medical Drug Policy; effective: July 13, 2025



COVERAGE

Reauthorization of therapy with VILTEPSO may be approved if the following criteria are met.

If the member meets Horizon NJ Health criteria, approval will be for up to 1 year of therapy.



Place a checkmark with the completion of each criterion.



CLINICAL RECORDS



Provide documentation that the patient remains ambulatory.*



Confirm the patient is using a corticosteroid concomitantly unless contraindicated or member is unable to tolerate therapy.



Confirm there is absence of unacceptable toxicity from the drug (ie, severe hypersensitivity reactions, renal toxicity/proteinuria, etc).



Submit documentation showing clinical improvement and/or response to therapy compared to pretreatment levels in one or more of the following:

1. Increase in dystrophin level
2. Stability, improvement, or slowed rate of decline in 6-Minute Walk Test or other timed function tests
3. Stability, improvement, or slowed rate of decline in upper limb function test
4. Stability, improvement, or slowed rate of decline in the North Star Ambulation Assessment

*With or without needing an assistive device, such as a cane or walker.



PRESCRIPTION

Please confirm that:



VILTEPSO is not being used concomitantly with any other exon-skipping agents (eg, Exondys 51® [eteplirsen], Vyondys 53® [golodirsen], Amondys 45® [casimersen]) for Duchenne muscular dystrophy (DMD).

[Fill a VILTEPSO prescription using our form >](#)

Checklist for Reauthorization of Treatment With VILTEPSO® (viltolarsen)



COVERAGE

Use the checklist below as a guide to assist you with identifying documentation that may be required for reauthorization or continuation of treatment with VILTEPSO. Please provide all documentation and/or attestations required by the patient's health plan coverage policy for VILTEPSO.



Place a checkmark with the completion of each criterion.



CRITERIA FOR INITIATION OF THERAPY WERE MET

☐

Individual is age 4-9 years.

☐

Individual is using a corticosteroid.

☐

Documentation is provided that individual is ambulatory.

☐

Individual is able to complete the following assessments:

A. Time to stand from supine

B. Time to run/walk 10 meters

C. Time to climb 4 stairs

☐

Individual will not use with any other exon-skipping agents for Duchenne muscular dystrophy (DMD) (including but not limited to Vyondys 53® [golodirsen]).



PRESCRIPTION

Please confirm that:

☐

Provide documentation of any additional motor function tests or clinical records deemed appropriate, including:

- Brooke Scale
- Pulmonary Function Tests (PFTs)
- Performance of Upper Limb (PUL)

NOTE: If upon requesting continuation of treatment, the patient is denied due to the inability to walk unassisted, you might consider using the letter of medical necessity directed to addressing treatment of non-ambulatory patients with VILTEPSO.

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Checklist for Continuation of Treatment With VILTEPSO® (viltolarsen)

Based on UnitedHealthcare's Medical Benefit Drug; effective: July 1, 2025



COVERAGE RATIONALE

For continuation of treatment with VILTEPSO for up to 12 months, all of the following criteria must be addressed.



Place a checkmark with the completion of each criterion.



CLINICAL RECORDS



Confirm that the patient has previously received treatment with VILTEPSO.



Submit medical records (eg, chart notes) confirming that the patient is ambulatory without needing an assistive device (eg, without side-by-side assist, cane, walker, wheelchair).



PRESCRIPTION

Please confirm that:



VILTEPSO is prescribed by, or in consultation with, a neurologist with expertise in the treatment of Duchenne muscular dystrophy (DMD) and Community Plan Policy.



VILTEPSO dosing for DMD is in accordance with the FDA-approved labeling.



VILTEPSO is not being used concomitantly with other exon-skipping therapies for DMD (eg, Amondys 45® [casimersen], Exondys 51® [eteplirsen], Vyondys 53® [golodirsen]).

Checklist for Reauthorization of Treatment With VILTEPSO® (viltolarsen)

NON-SPECIFIC PAYER
 **Viltepso®**
 (viltolarsen) injection



COVERAGE

Use the checklist below as a guide to assist you with identifying documentation that may be required for reauthorization or continuation of treatment with VILTEPSO. Please provide all documentation and/or attestations required by the patient's health plan coverage policy for VILTEPSO.



Place a checkmark with the completion of each criterion.



CRITERIA FOR INITIATION OF THERAPY WERE MET



Individual is age 4-9 years.



Individual is using a corticosteroid.



Documentation is provided that individual is ambulatory.



Individual is able to complete the following assessments:

A. Time to stand from supine

B. Time to run/walk 10 meters

C. Time to climb 4 stairs



Individual will not use with any other exon-skipping agents for Duchenne muscular dystrophy (DMD) (including but not limited to Vyondys 53® [golodirsen]).



PRESCRIPTION

Please confirm that:



Provide documentation of any additional motor function tests or clinical records deemed appropriate, including:

- Brooke Scale
- Pulmonary Function Tests (PFTs)
- Performance of Upper Limb (PUL)

NOTE: If upon requesting continuation of treatment, the patient is denied due to the inability to walk unassisted, you might consider using the letter of medical necessity directed to addressing treatment of non-ambulatory patients with VILTEPSO.

[Fill a VILTEPSO prescription using our form >](#)

Indication

VILTEPSO® (viltolarsen) 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, see full [Prescribing Information](#).



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