NS Pharma

Announcing: Permanent J-code for VILTEPSO® (viltolarsen)

NS Pharma is pleased to announce that the Centers for Medicare and Medicaid Services has designated a permanent J-code for VILTEPSO® (viltolarsen) for intravenous infusion.

Level II HCPCS code: J1427 (Injection, Viltolarsen)

As of April 1, 2021, healthcare providers may use this code when submitting for reimbursement for VILTEPSO. Please refer to the product codes below. This code replaces J-code, J3490 or any other miscellaneous codes.

Coding Information for VILTEPSO	
NDC code for VILTEPSO (11-digit)	**73292-0011-01** VILTEPSO (250 mg/5 mL [50 mg/mL] single-dose vial)
HCPCS code for VILTEPSO	**J1427** Injection, Viltolarsen; bills in 10 mg units
Package	**Single-dose Vial** 250 mg/5 mL (50 mg/mL)

If you have questions or require additional information, please contact your NS Pharma representative or email info@nspharma.com.

INDICATION

VILTEPSO is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with VILTEPSO. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

IMPORTANT SAFETY INFORMATION

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

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

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

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

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

To report suspected adverse reactions or product complaints, contact NS Pharma, Inc., at 866-677-4276. You may also report suspected adverse reactions to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Viltepso® (viltolarsen) injection