

Permanent J-code Available for ZOLGENSMA



Use code
J3399: Injection, onasemnogene abeparvovec-xioi,
up to 5×10^{15} vector genomes¹

The Centers for Medicare & Medicaid Services (CMS) has assigned a permanent, product-specific J-code for ZOLGENSMA® (onasemnogene abeparvovec-xioi). Use of this code may help ensure timely reimbursement for ZOLGENSMA.



J3399 is effective **July 1, 2020**



J3399 is specific to **ZOLGENSMA**



Please contact the OneGene Program™ at 855-441-GENE (4363) at any time to be connected with a Field Reimbursement Manager for additional assistance.

Utilization of the J-code is required when billing for ZOLGENSMA. Please ensure the billing system at your organization has been updated accordingly to support accurate coding and billing processes. The permanent J-code for ZOLGENSMA may also be found on the CMS website at: <https://www.cms.gov/Medicare/Coding/HCPSCReleaseCodeSets/HCPSC-Quarterly-Update>.

Please see Indication and Important Safety Information, including Boxed Warning for Acute Serious Liver Injury, on next page and the accompanying Full Prescribing Information.

Indication and Important Safety Information

Indication

ZOLGENSMA® (onasemnogene abeparvovec-xioi) is an adeno-associated virus vector-based gene therapy indicated for the treatment of pediatric patients less than 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the *survival motor neuron 1 (SMN1)* gene.

Limitations of Use

The safety and effectiveness of repeat administration or the use in patients with advanced SMA (e.g., complete paralysis of limbs, permanent ventilator dependence) has not been evaluated with ZOLGENSMA.

Important Safety Information

BOXED WARNING: Acute Serious Liver Injury

Acute serious liver injury and elevated aminotransferases can occur with ZOLGENSMA. Patients with pre-existing liver impairment may be at higher risk. Prior to infusion, assess liver function of all patients by clinical examination and laboratory testing (e.g., hepatic aminotransferases [aspartate aminotransferase (AST) and alanine aminotransferase (ALT)], total bilirubin, and prothrombin time). Administer a systemic corticosteroid to all patients before and after ZOLGENSMA infusion. Continue to monitor liver function for at least 3 months after infusion.

WARNINGS AND PRECAUTIONS

Thrombocytopenia

Transient decreases in platelet counts, some of which met the criteria for thrombocytopenia, were observed at different time points after ZOLGENSMA infusion. Monitor platelet counts before ZOLGENSMA infusion and on a regular basis for at least 3 months afterwards.

Elevated Troponin-I

Transient increases in cardiac troponin-I levels were observed following ZOLGENSMA infusion. Monitor troponin-I before ZOLGENSMA infusion and on a regular basis for at least 3 months afterwards.

ADVERSE REACTIONS

The most commonly observed adverse reactions (incidence $\geq 5\%$) in clinical studies were elevated aminotransferases and vomiting.

Please see accompanying Full Prescribing Information.

Reference: Centers for Medicare & Medicaid Services website. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>. Accessed May 26, 2020.