# Permanent J-code Available for ZOLGENSMA

zolgensma® (onasemnogene abeparvovec-xioi)

**Use code J3399: Injection, onasemnogene abeparvovec-xioi, up to $5x10^{15}$ vector genomes[1]**

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** has been in effect since **July 1, 2020**

**J3399** is specific to **ZOLGENSMA**

*Please contact your Novartis Gene Therapies Regional Account Associate Director (RAAD) 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/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update.

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

# Indication and Important Safety Information

zolgensma® (onasemnogene abeparvovec-xioi)

## 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.

**Thrombotic Microangiopathy**

Cases of thrombotic microangiopathy (TMA) were reported approximately 1 week after ZOLGENSMA infusion. Obtain baseline creatinine and complete blood count before ZOLGENSMA infusion. Following infusion, monitor for thrombocytopenia as well as other signs and symptoms of TMA. Consult a pediatric hematologist and/or pediatric nephrologist immediately to manage if clinically indicated.

**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 ≥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 March 18, 2021.

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