CIGNA COMPLEX DRUGS AND BIOLOGICS PROVIDER INFORMATION REVIEW

Zolgensma® (onasemnogene abeparvovec-xioi)

June 2019

On May 24, 2019, the U.S. Food and Drug Administration (FDA) approved Zolgensma® (onasemnogene abeparvovec-xioi) for the treatment of pediatric patients less than 2 years of age with spinal muscular atrophy (SMA), including those who are pre-symptomatic at diagnosis. This gene replacement therapy uses a specially tailored, therapeutic virus, given intravenously through a one-time infusion, to deliver the missing survival motor neuron 1 (SMN1) gene into a patient's cells. The body can then use the new SMN1 gene to make SMN protein to preserve muscle function.

Brand (generic) name	Zolgensma (onasemnogene abeparvovec-xioi)
Manufacturer	Novartis
Indication	Zolgensma 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. 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.
Dosing and administration	Dosing is determined by patient weight. Zolgensma is a single-dose intravenous infusion administered only by a health care provider. Zolgensma is administered as a slow infusion over 60 minutes.

1. **What is the cost of Zolgensma?**
   The wholesale acquisition cost (WAC) of Zolgensma is $2,125,000 per dose. In addition to the drug cost, there may be additional facility charges associated with administration of the drug.

2. **How is Zolgensma covered?**
   Zolgensma is covered under the Cigna medical benefit for eligible customers after prior authorization requirements are met. Because Zolgensma must be administered by a health care provider, it is not covered under the pharmacy benefit.

3. **How do providers request prior authorization for Zolgensma?**
   Providers must send a prior authorization request through the Cigna Pharmacy Service Center via fax to the dedicated Zolgensma Intake Team at 1.866.544.1204. Prior authorization forms are available on the Cigna for Health Care Professionals website (CignaforHCP.com > Forms Center > Pharmacy Forms > Pharmacy Prior Authorization Forms).

4. **How is Zolgensma procured?**
   Facilities must procure Zolgensma through Accredo, which is one of two specialty pharmacies designated by Novartis to distribute the drug. Accredo will submit the drug claim directly to Cigna for reimbursement. We will not reimburse facilities that purchase Zolgensma directly from specialty pharmacies, manufacturers, or wholesalers unless otherwise required by law. This follows our Limited Distribution Drugs with Reimbursement Restriction guidelines in the Cigna Reference Guide for providers.

5. **Who can administer Zolgensma?**
   Novartis determines the facilities in the United States authorized to administer the gene therapy. Providers should verify if facility participates in the Cigna network.

Together, all the way.