# Cigna Healthcare Gene Therapy Prior Auth Request Form

**This therapy requires supportive documentation (chart notes, genetic test results, etc.).**

****Due to privacy regulations we will not be able to respond via fax with the outcome of our review unless all asterisked (*) fields on this form are completed****

## Gene Therapy Prior Authorization

To allow more efficient and accurate processing of your medication request, please complete this form and fax it back along with copies of all supporting clinical documentation. Fax completed form to Fax# 833-910-1625.

Notice: Failure to complete this form in its entirety may result in delayed processing or an adverse determination for insufficient information.

Gene Therapy Product Name **Zolgensma**

Cigna has designated the above product to be a gene therapy product, which is included in the Cigna Gene Therapy Provider Network.

Questions pertaining to gene therapy may be directed to the dedicated Gene Therapy Program team at 855.678.0051 or email to GeneTherapyProgram@Cigna.com

| PHYSICIAN INFORMATION | | | PATIENT INFORMATION | | |
|---|---|---|---|---|---|
| * Physician Name: | | | *Due to privacy regulations we will not be able to respond via fax with the outcome of our review unless all asterisked (*) items on this form are completed.* | | |
| Specialty: | * DEA, NPI or TIN: | | | | |
| Office Contact Person: | | | * Customer Name: | | |
| Office Phone: | | | * Cigna ID: | *Customer Date of Birth: | |
| Office Fax:<br>*Is your fax machine kept in a secure location?<br>☐ Yes<br>☐ No<br><br>*May we fax our response to your office?<br>☐ Yes<br>☐ No | | | * Customer/Patient Street Address: | | |
| Office Street Address: | | | City: | State: | Zip: |
| City: | State: | Zip: | Patient Phone: | | |

**Urgency:**
☐ Standard ☐ Urgent (In checking this box, I attest to the fact that applying the standard review time frame may seriously jeopardize the customer's life, health, or ability to regain maximum function)

**Where will this medication be obtained?**
☐ Accredo Specialty Pharmacy**
☐ Other (please specify):

ICD10:

***Cigna's nationally preferred specialty pharmacy*

**Name of Facility administering medication:**
Facility Name: State: Tax ID#:
Address (City, State, Zip Code):

**Clinical Information – Zolgensma** (Onasemnogene Abeparvovec-xioi)

Does your patient have a documented diagnosis of Spinal Muscular Atrophy (SMA)?
☐ Yes
☐ No
☐ Unknown

Is your patient less than 2 years of age?
☐ Yes
☐ No

If your patient is a premature neonate, has full term gestational age been met?
☐ Yes
☐ No
☐ Does not apply

Is there documentation of genetic test confirming the diagnosis of spinal muscular atrophy with bi-allelic pathogenic variants in the survival motor neuron 1 (SMN1) gene? (Please include copy of these results)
☐ Yes
☐ No
☐ Unknown

Is there documentation of genetic test confirming three or fewer survival motor neuron 2 (SMN2) gene copies? (Please include copy of these results)
☐ Yes
☐ No
☐ Unknown

Is there documentation of genetic test confirming four survival motor neuron 2 (SMN2) gene copies? (Please include copy of these results)
☐ Yes
☐ No
☐ Unknown

Is there documentation the number of survival motor neuron (SMN2) gene copies has been determined by a quantitative assay capable of distinguishing between four SMN2 gene copies and five or greater SMN2 copies? (Please include copy of these results)
☐ Yes
☐ No
☐ Unknown

Is there documentation of **ALL** of the following prior to the administration of Zolgensma? (Please include copy of these results)
☐ Baseline anti-AAV9 antibody titers are less than or equal to 1:50
☐ Liver function assessment within the last 30 days demonstrating alanine aminotransferase (ALT) levels are no greater than 2 times the upper limit of normal
☐ Liver function assessment within the last 30 days demonstrating aspartate aminotransferase (AST) levels are no greater than 2 times the upper limit of normal
☐ Liver function assessment within the last 30 days demonstrating total bilirubin levels are no greater than 2 times the upper limit of normal. (Individuals with elevated bilirubin levels due to neonatal jaundice are acceptable).
☐ Liver function assessment within the last 30 days demonstrating prothrombin results are no greater than 2 times the upper limit of normal
☐ Renal function assessment within the last 30 days demonstrating a creatinine level of less than 1.0mg/dl
☐ Complete blood count within the last 30 days demonstrating white blood cell count no greater than 20,000 cells/$mm^3$
☐ Complete blood count within the last 30 days demonstrating Hemoglobin levels between 8g/dL and 18g/dL

According to the prescriber **ALL** of the following apply:
☐ Prophylactic systemic corticosteroids, equivalent to oral prednisone at a dose of 1mg/kg/day, will commence 1 day prior to Zolgensma infusion and will continue daily for a total of 30 days.
☐ No previous use of Onasemnogene Abeparvovec-xioi (Zolgensma)
☐ If your patient is currently receiving, or has received, treatment with Spinraza (nusinersen injection for intrathecal use), further therapy with Spinraza will be discontinued
☐ If your patient is currently receiving, or has received, treatment with Evrysdi® (risdiplam oral solution), further therapy with Evrysdi will be discontinued
☐ Submission of medical records (including, but not limited to): chart notes (including developmental motor milestones), laboratory data, genetic testing results
☐ Agreement to share required plan specific treatment outcome measures

Medication is prescribed by, or in consultation with, a physician who specializes in the management of patients with spinal muscular atrophy and/or neuromuscular disorders?
☐ Yes
☐ No
☐ Unknown

Do any of the following apply to your patient? (Check all that apply)
☐ Complete paralysis of limbs
☐ Has permanent ventilator dependence. Permanent ventilation is defined as requiring invasive ventilation (tracheostomy), or respiratory assistance for 16 or more hours per day (including noninvasive ventilatory support) continuously for 14 or more days in the absence of an acute reversible illness, excluding perioperative ventilation.
☐ None of the above apply to your patient

**If any of the requirements listed above are not met and provider feels administration of Zolgensma is medically necessary please provide clinical support and rationale for the use of Zolgensma.**

Additional pertinent information: *(including disease stage, prior therapy, performance status, and names/doses/admin schedule of any agents to be used concurrently)*

**Additional Attestation required for Embarc Benefit Protection* Criteria when applicable**

According to the prescribing physician:
☐ If your patient is currently receiving, or has received, treatment with Spinraza (nusinersen injection for intrathecal use), further therapy with Spinraza will be discontinued
☐ If your patient is currently receiving, or has received, treatment with Evrysdi® (risdiplam oral solution), further therapy with Evrysdi will be discontinued
☐ No previous use of Onasemnogene Abeparvovec-xioi (Zolgensma)

**For additional information on Embarc Benefit Protection refer to the Cigna Reference Guide of physicians, physicians, hospitals, ancillaries, and other health care providers. This guide is available at CignaforHCP.com > Resources > Reference Guides > Medical Reference Guides: View Documents > Health Care Professional Reference Guides. Providers must log in to access.*

## Agreement and Attestation

Do you and your patient agree to share any required plan specific outcome measures?
☐ Yes
☐ No

Attestation: I attest the information provided is true and accurate to the best of my knowledge. I understand that the Health Plan or insurer its designees may perform a routine audit and request the medical information necessary to verify the accuracy of the information reported on this form.

**Prescriber Signature:**_____ **Date:**_____

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