Cigna Healthcare Zolgensma Gene Therapy Prior Auth
This therapy requires supportive documentation (chart notes, genetic test results, etc.).

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

<table>
<tr><th colspan="3">PHYSICIAN INFORMATION</th><th colspan="3">PATIENT INFORMATION</th></tr>
<tr><td colspan="3">*Physician Name:</td><td colspan="3" rowspan="2">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.</td></tr>
<tr><td>Specialty:</td><td colspan="2">*DEA, NPI or TIN:</td></tr>
<tr><td colspan="3">Office Contact Person:</td><td colspan="3">*Customer Name:</td></tr>
<tr><td colspan="3">Office Phone:</td><td>*Cigna ID:</td><td colspan="2">*Customer Date of Birth:</td></tr>
<tr><td colspan="3">Office Fax:
*Is your fax machine kept in a secure location:
☐ Yes
☐ No

*May we fax our response to your office?
☐ Yes
☐ No</td><td colspan="3">*Customer / Patient Street Address:</td></tr>
<tr><td colspan="3">Office Street Address:</td><td>City:</td><td>State:</td><td>Zip:</td></tr>
<tr><td>City:</td><td>State:</td><td>Zip:</td><td colspan="3">Patient Phone:</td></tr>
<tr><td colspan="6">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)</td></tr>
<tr><td colspan="6">Where will this medication be obtained?
□ Accredo
□ Other</td></tr>
</table>

Where will this medication be administered?
Facility Name:
Address: State:
Tax ID#:

What location will this medication be administered?
□ Outpatient Hospital □ Inpatient Hospital □ MD Office / Clinic
□ Home □ Other

ICD 10 Associated with the Indication of this request:

Zolgensma is considered medically necessary when the following criteria are met, check all that apply:

□ Patient is less than 2 years of age; AND

□ If the patient is a premature neonate, full-term gestation age of 39 weeks and 0 days has been met; AND
Note: Full-term gestational age can be defined as the postmenstrual age (gestational age plus chronological age) being equal to ≥ 39 weeks and 0 days.

□ Patient has not received Zolgensma in the past **[verification in claims history required]**; AND
Note: If no claim for Zolgensma is present (or if claims history is not available), the prescribing physician confirms that the patient has not previously received Zolgensma.

□ Patient has had a genetic test confirming the diagnosis of spinal muscular atrophy with bi-allelic pathogenic variants in the survival motor neuron 1 (SMN1) gene **[documentation required]**; AND
Note: Pathogenic variants may include homozygous deletion, compound heterozygous mutation, or a variety of other rare mutations.

□ Patient meets ONE of the following (i or ii):
- □ i. Patient has three or fewer survival motor neuron 2 (SMN2) gene copies **[documentation required]**; OR
- □ ii. Patient meets BOTH of the following (a and b):
  - □ a. Patient has four SMN2 gene copies **[documentation required]**; AND
  - □ b. The number of SMN2 gene copies has been determined by a quantitative assay capable of distinguishing between four SMN2 gene copies and five or greater SMN2 gene copies; AND

□ According to the prescribing physician, patient has started or will receive systemic corticosteroids equivalent to oral prednisolone at a dose of 1 mg/kg per day commencing 1 day prior to Zolgensma infusion and for a total of 30 days; AND

□ Baseline anti-AAV9 antibody titers are ≤ 1:50 **[documentation required]**; AND
□ Patient has undergone liver function testing within the past 30 days and meets ALL of the following (i, ii, iii, and iv):
- □ i. Alanine aminotransferase levels are ≤ 2 times the upper limit of normal **[documentation required]**; AND
- □ ii. Aspartate aminotransferase levels are ≤ 2 times the upper limit of normal **[documentation required]**; AND
- □ iii. Total bilirubin levels are ≤ 2 times the upper limit of normal **[documentation required]**; AND *Note: Patient with elevated bilirubin levels due to neonatal jaundice are acceptable.*
- □ iv. Prothrombin time results are ≤ 2 times the upper limit of normal **[documentation required]**; AND

□ Patient has undergone a renal function assessment within the past 30 days and has a creatinine level < 1.0 mg/dL **[documentation required]**; AND

□ A complete blood count has been obtained within the past 30 days and the patient meets BOTH of the following (i and ii):
- □ i. White blood cell count is ≤ 20,000 cells per mm^3 **[documentation required]**; AND
- □ ii. Hemoglobin levels are between 8 g/dL and 18 g/dL **[documentation required]**; AND

□ For a patient currently receiving or who has received prior treatment with Spinraza (nusinersen intrathecal injection), the prescribing physician confirms that further therapy with Spinraza will be discontinued; AND

□ For a patient currently receiving or who has received prior treatment with Evrysdi (risdiplam oral solution), the prescribing physician confirms that further therapy with Evrysdi will be discontinued; AND

□ Medication is prescribed by a physician who has consulted with or who specializes in the management of patients with spinal muscular atrophy and/or neuromuscular disorders; AND

□ Current patient body weight has been obtained within the past 14 days **[documentation required]**;

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

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

Any other use is considered experimental, investigational, or unproven, including the following, check all that apply:

□ **Patient has Complete Paralysis of All Limbs.** This is cited as a limitation of use in the Zolgensma prescribing information.[1] Data are needed to determine if this patient population would derive benefits from Zolgensma.

□ **Patient has Permanent Ventilator Dependence.** This is cited as a limitation of use in the Zolgensma prescribing information.[1] Data are needed to determine if this patient population would derive benefits from Zolgensma.

□ **Administration in Individuals in Utero.** Zolgensma is not approved for in utero administration per the prescribing information.

□ **Prior Receipt of Gene Therapy.** Zolgensma has not been studied in patients who previously received gene therapy.

If any of above apply to your customer, please provide clinical support and rationale for the use of this gene therapy.

Additional CPT and Administration Codes for Consideration Following Medical Necessity Determination:

Provide all associated CPT codes for administration of Zolgensma

Additional Attestation required for Embarc Benefit Protection*.

The prescribing physician confirms that the patient has not previously received Zolgensma?
□ Yes
□ No
□ Unknown

**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

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: _____