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

Program to	<u>eam at 855.</u>	678.0051 or email to	<u>Gene i nera</u>	apyProgram@	<u>Cigna.com</u>	
P	HYSICIAN II	NFORMATION	PATIENT INFORMATION			
*Physician Specialty:	Name:	*DEA, NPI or TIN:	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.			
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Office Conta	act Person:		*Customer Name:			
Office Phon	e:		*Cigna II		*Customer Date of Birth:	
Office Fax: *Is your fax machine kept in a secure location:			*Customer / Patient Street Address:			
☐ Yes						
□ No						
*May we fax	our response to	your office?				
☐ Yes						
□ No						
Office Street Address:			City:	State:		Zip:
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Where will □ Accredo □ Other	this medicat	ion be obtained?				

Where will this medication be administered?						
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 Nate: 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 pot preceived Zolgensma in the past Verification in claims history required]; AND Nate: fin o claim for Zolgensma is present (or if claims history is not available), the prescribing physician confirms that the patient has ngt previously received Zolgensma. □ Patient has had a genetic test confirming the diagnosis of spinal muscular atroph with bi-allelic pathogenic variants in the survival motor neuron 1 (SMM1) gene (focumentation required]; AND Nate: Pathogenic variants may include homozygous deletion, compound heterozygous mutation, or a variety of other rare mutations. □ Patient has three or fewer survival motor neuron 2 (SMN2) gene copies [documentation required]; OR □ II. Patient has four SMN2 gene copies Idocumentation required]; OR □ II. Patient has four 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 □ 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 day	Where will this medic	ation be administered?				
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 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 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. Patient has t	three or fewer survival motor neuron 2 (SMN2) gene copies [documentat	tion required]; OR			
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	□ II. H€	emoglobin levels are between 8 g/aL and 18 g/aL tdocumentation requi	reaj; AND			
	□ For a natient current	tly receiving or who has received prior treatment with Spinraza (pusi	nersen intrathecal			

□ 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 Attack the construction of the England Box (1) Box (1) and
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:

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