PRESCRIPTION FORM: INSTRUCTIONS

zolgensma® (onasemnogene abeparvovec-xioi) suspension for intravenous infusion

To learn more about the OneGene Program®, call 855-441-GENE (4363), Monday-Friday (8 AM to 8 PM ET).

The OneGene Program®, offered by Novartis Gene Therapies, is a comprehensive, individualized support program for families with pediatric patients less than 2 years of age with spinal muscular atrophy (SMA) and their health care providers throughout the ZOLGENSMA® (onasemnogene abeparvovec-xioi) treatment journey. OneGene Program® support includes:

- Answers to questions about ZOLGENSMA
- A dedicated, personalized support team focused on the needs of each family
- Verification of insurance benefits
- Coordination of financial assistance programs for eligible patients

The Patient Consent Form, provided on page 3, can be submitted with the ZOLGENSMA Prescription Form by the Prescriber's office, or separately by the patient's parent/legal guardian. A signed Patient Consent Form is needed in order to receive support through the OneGene Program®.

SEE PAGE 2

INSTRUCTIONS FOR HEALTH CARE PROVIDERS

ZOLGENSMA PRESCRIPTION FORM FOR PRESCRIBERS—required for all patients who are prescribed ZOLGENSMA.

The ZOLGENSMA Prescription Form must be submitted by Prescriber office only.

Section: Billing Method

- ☑ Select your preferred billing method: Buy and Bill or a Specialty Pharmacy. **Please note that the billing method may be specified by the patient's insurance plan.**

Section 1: Patient Information

- ☑ Patient and parent/legal guardian contact information, including phone numbers and email address, is required in this section. A signed Patient Consent Form is needed in order for a patient to receive support through the OneGene Program®.
- ☑ **Please give the Patient Consent Form, provided on page 3, to the parent/legal guardian. If the parent/legal guardian is not available to sign the consent form, it will be provided to them separately by the OneGene Program®.**

Section 2: Insurance Information

- ☑ Be sure to complete the patient's insurance information, and indicate if the patient has secondary coverage by checking the box; OR
- ☑ **Include copies of both sides of the patient's medical and pharmacy insurance card(s).**

Section 3: Prescriber/Institution Information

- ☑ Prescriber and Institution contact information is required in this section.
- ☑ Be sure to include Tax ID and NPI numbers to help facilitate the benefits investigation process.

Section 4: Lab Results Documentation

- ☑ The following tests may be required by the insurance provider. Please indicate on the ZOLGENSMA Prescription Form which, if any, of the following tests have been ordered or completed:
  - Spinal Muscular Atrophy (SMA) Diagnostic Test, which includes: *SMN1* deletion and *SMN2* copy number
  - AAV9 Antibody Test

Novartis Gene Therapies is offering the Novartis Gene Therapies Laboratory Testing Program to facilitate efficient testing and reimbursement. For more information, please call the OneGene Program® at 855-441-GENE (4363).

Section 5: Prescription Information

This section serves as the official prescription for ZOLGENSMA. *The Prescriber is to comply with his/her state-specific prescription requirements, such as e-prescribing, state-specific prescription form, fax language, etc. Noncompliance with state-specific requirements may result in outreach to the Prescriber.*

- ☑ **All fields on page 2 are required. Please be sure to sign, date, and fax the form to 855-951-GENE (4363).**

For more information, please see the ZOLGENSMA Treatment Guide and Full Prescribing Information.

Please fax signed ZOLGENSMA Prescription Form as soon as it has been completed to 855-951-GENE (4363).
If you have any questions or would like to learn more, call 855-441-GENE (4363), Monday-Friday (8 AM to 8 PM ET).
The Patient Consent Form is not required to begin the prescription process for ZOLGENSMA.

Please see Indication and Important Safety Information, including Boxed Warning for Acute Serious Liver Injury and Acute Liver Failure, on page 4 and the accompanying Full Prescribing Information.

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PRESCRIPTION FORM

Please be sure to sign, date, and fax the form to 855-951-GENE (4363).

Form must be submitted by Prescriber's office only.

zolgensma® (onasemnogene abeparvovec-xioi)
suspension for intravenous infusion

To learn more about the OneGene Program®, call 855-441-GENE (4363), Monday-Friday (8 AM to 8 PM ET).

Please Select Billing Method: ❑ Buy and Bill | Preferred Specialty Pharmacy ❑ Accredo ❑ Orsini

Please note: Product is available through limited Specialty Pharmacies. Actual billing method may be specified by the patient's insurance.

1 PATIENT INFORMATION

Patient Name: Gender: ❑ Male ❑ Female **Date of Birth: / /**

Patient Address:_____ City: _____ State: _____ ZIP: _____

Parent/Legal Guardian: _____ Relationship: ❑ Power of Attorney ❑ Other: _____

Home Phone #: _____ Cell Phone #: _____ Email: _____

Preferred language: ❑ English ❑ Spanish ❑ Other: _____

2 INSURANCE INFORMATION

(Please attach a copy of both sides of the patient's medical and pharmacy insurance card(s) via fax with this prescription form.)

Primary Insurance ❑ Patient has secondary insurance coverage–check if yes

Insurance Provider: _____ Phone #: _____ Policy ID #: _____ Group #: _____

Policy Holder Name: _____ Policy Holder Date of Birth: ____/____/____ Policy Holder Relationship to Patient: _____

3 PRESCRIBER/INSTITUTION INFORMATION

Prescriber Name: Tax ID #: _____ **NPI #:**

Prescriber Address: _____ City: _____ State: _____ ZIP:_____

Prescriber Email: _____ Office Contact Name: _____ Office Contact Phone #: _____

Fax #:_____ Office Contact Email: _____ Institution Name: _____

Institution Address: _____ City: _____ State: _____ ZIP:_____

Product Shipping/Receiving Contact Name: _____ Product Shipping/Receiving Contact Phone #: _____

4 LAB RESULTS DOCUMENTATION

Please fax genetic SMA confirmation and AAV9 Antibody Test results on file to OneGene Program®: 855-951-GENE (4363). The following tests may be required by the insurance provider.

Please confirm which tests have been ordered or completed, if any: Spinal Muscular Atrophy (SMA) Diagnostic Test which includes *SMN1* deletion and *SMN2* copy number: ❑ Ordered ❑ Completed AAV9 Antibody Test: ❑ Ordered ❑ Completed

Please call OneGene Program® at 855-441-GENE (4363), Monday-Friday (8 AM to 8 PM ET), if you have questions on the AAV9 Antibody Test or other tests.

5 ZOLGENSMA PRESCRIPTION INFORMATION

Primary Diagnosis ICD-10 Code: ❑ **G.12.0 Infantile SMA type 1 (Werdnig-Hoffman)** ❑ **Other (Include ICD code):**

Patient Current/Prior SMA Treatment (medication): ❑ **Treatment-naive**

Patient Allergies: ❑ **No known allergies**

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. ZOLGENSMA is provided in a kit containing 2 to 9 vials, as a combination of 2 vial sizes (either 5.5 mL or 8.3 mL). Patients less than 2 years of age weighing equal to or greater than 13.6 kg will require a combination of ZOLGENSMA kits. All vials have a nominal concentration of 2.0×10^{13} vg/mL. ZOLGENSMA is for single-dose intravenous infusion only and is administered as a slow infusion over approximately 60 minutes.

Quantity: 1 **Refills: No Refills**

Patient Weight: kg **Date Weight Taken: / /** **Expected Infusion Date: / /**

Please check a box or boxes below to indicate patient dose. The intravenous dosage is determined by patient body weight:

Patient Weight Range (kg)	NDC Number	Patient Weight Range (kg)	NDC Number	Patient Weight Range (kg)	NDC Number	Patient Weight Range (kg)	NDC Number	Patient Weight Range (kg)	NDC Number
❑ 2.6 – 3.0	71894-120-02	❑ 5.1 – 5.5	71894-125-04	❑ 7.6 – 8.0	71894-130-06	❑ 10.1 – 10.5	71894-135-07	❑ 12.6 – 13.0	71894-140-09
❑ 3.1 – 3.5	71894-121-03	❑ 5.6 – 6.0	71894-126-04	❑ 8.1 – 8.5	71894-131-06	❑ 10.6 – 11.0	71894-136-08	❑ 13.1 – 13.5	71894-141-09
❑ 3.6 – 4.0	71894-122-03	❑ 6.1 – 6.5	71894-127-05	❑ 8.6 – 9.0	71894-132-06	❑ 11.1 – 11.5	71894-137-08		
❑ 4.1 – 4.5	71894-123-03	❑ 6.6 – 7.0	71894-128-05	❑ 9.1 – 9.5	71894-133-07	❑ 11.6 – 12.0	71894-138-08		
❑ 4.6 – 5.0	71894-124-04	❑ 7.1 – 7.5	71894-129-05	❑ 9.6 – 10.0	71894-134-07	❑ 12.1 – 12.5	71894-139-09		

See ZOLGENSMA Treatment Guide for a complete description of kit contents.

By signing below, I certify that the above therapy is medically necessary and that I will supervise the patient's treatment accordingly.

SIGN

OR

Prescriber Signature—Dispense as Written (No Stamp Allowed) **Date**

Prescriber Signature—Generic Substitution Allowed (No Stamp Allowed) Date

The Prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Noncompliance with state-specific requirements may result in outreach to the Prescriber.

I authorize Novartis Gene Therapies and OneGene Program® as my designated agent and on behalf of my patient to forward the above prescription, by fax or by any means under applicable law, to the appropriate pharmacy, vendor or partner.

PATIENT CONSENT FORM

This form provides consent to share health information for the purpose of providing patient support and marketing or other communication.

zolgensma® (onasemnogene abeparvovec-xioi) suspension for intravenous infusion

To learn more about the OneGene Program®, call 855-441-GENE (4363), Monday-Friday (8 AM to 8 PM ET).

Enroll in the OneGene Program® today by sending this signed Patient Consent Form by:

Fax to 855-951-GENE (4363) **Mail to OneGene Program® at 4700 North Hanley Road, Berkeley, MO 63134**

Consent to share health information for the purpose of providing patient support and marketing or other communication:

I hereby authorize my (and/or my child's) healthcare providers, health insurance carriers, and pharmacy providers to use and disclose my (and/or my child's) individually identifying health information, including health insurance information, medical diagnosis and condition (including lab test results related to such diagnosis or supportive testing), prescription information, and name, address, and telephone number to Novartis Gene Therapies, Inc. (hereinafter "Novartis Gene Therapies") and its agents and representatives, including third parties authorized by Novartis Gene Therapies to administer the OneGene Program®, in order to administer the OneGene Program® patient and ZOLGENSMA® (onasemnogene abeparvovec-xioi) support program for the following purposes: 1) to contact my (and/or my child's) healthcare provider and collect, enter, and maintain my (and/or my child's) health information in a database; 2) to contact my (and/or my child's) insurers as needed to verify my (and/or my child's) insurance coverage, review reimbursement requirements, and assist with the processing of claims; 3) to determine eligibility for program offerings, including financial assistance services; 4) to contact me by telephone or email, in electronic format or otherwise, to receive education, study the effectiveness of therapy, assess OneGene Program® customer service, and to provide therapy support services designed for people prescribed ZOLGENSMA; 5) to occasionally contact me by mail, email, fax, telephone call, and text message for marketing or market research purposes and to provide me with information about program services and/or other topics of interest; 6) to perform data analytics with aggregated de-identified data to assess program efficiency; and 7) to provide the patient with ongoing therapy support. All prescription related support is limited to Novartis Gene Therapies product(s).

OneGene Program® and Novartis Gene Therapies agree to protect my (and/or my child's) health information by using and disclosing such information only for the reasons listed above, pursuant to the requirements imposed under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). I understand that federal privacy laws may no longer protect my (and/or my child's) health information after its disclosure to OneGene Program® and that it may be subject to redisclosure.

I understand that I am entitled to a copy of this signed Authorization and may revoke (withdraw) this Authorization at any time by faxing a signed, written request to OneGene Program® at 855-951-GENE (4363) or by mailing such request to OneGene Program® at 4700 North Hanley Road, Berkeley, MO 63134. OneGene Program® will no longer seek disclosure of my (and/or my child's) health information from his/her healthcare providers and health insurance carriers once it has received and processed my revocation. However, revoking this Authorization will not affect any use and disclosure of the health information that has already occurred in reliance on my authorization. If I revoke this Authorization, I will no longer be able to receive OneGene Program® support services.

This Authorization shall be valid for ten (10) years from the date indicated next to my signature below unless earlier revoked by my written request or in accordance with local laws.

No effect on treatment: I understand I do not have to sign this Authorization and that my enrollment in any of the services and/or programs described above is entirely voluntary. I understand that Novartis Gene Therapies, as well as my (and/or my child's) healthcare providers, cannot require me, as a condition of having access to medications, prescription drugs, treatment or other care, to sign this Authorization. Federal Law (including HIPAA) requires a signed authorization in order for OneGene Program® to collect this information from my (and/or my child's) healthcare providers. I understand I cannot participate in the listed services and/or programs without signing this Authorization or an equivalent authorization with my (and/or my child's) healthcare providers.

I understand that my pharmacy, health insurers, and third party vendors may receive remuneration (payment) from the OneGene Program® and Novartis Gene Therapies in exchange for disclosing my Personal Information to the OneGene Program® and Novartis Gene Therapies and/or for providing me with support services for the purposes described above.

PATIENT INFORMATION

_____ _____/_____/_____

Patient Name (Please Print) **Patient Date of Birth**

_____ _____

Parent/Legal Guardian Name (Please Print) **Relationship to Patient**

SIGN

_____ _____/_____/_____

Parent/Legal Guardian Signature **Date**

_____ (_____)_____ (_____)_____

Parent/Legal Guardian Email Address (optional) Home Phone (optional) Mobile Phone (optional)

Please see Indication and Important Safety Information, including Boxed Warning for Acute Serious Liver Injury and Acute Liver Failure, on page 4 and the accompanying Full Prescribing Information.

Indication and Important Safety Information

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What is ZOLGENSMA® (onasemnogene abeparvovec-xioi)?

ZOLGENSMA is a prescription gene therapy used to treat children less than 2 years old with spinal muscular atrophy (SMA). ZOLGENSMA is given as a one-time infusion into a vein. ZOLGENSMA was not evaluated in patients with advanced SMA.

What is the most important information I should know about ZOLGENSMA?

- ZOLGENSMA can increase liver enzyme levels and cause acute serious liver injury or acute liver failure.
- Patients will receive an oral corticosteroid before and after infusion with ZOLGENSMA and will undergo regular blood tests to monitor liver function.
- Contact the patient's doctor immediately if the patient's skin and/or whites of the eyes appear yellowish, if the patient misses a dose of corticosteroid or vomits it up, or if the patient experiences a decrease in alertness.

What should I watch for before and after infusion with ZOLGENSMA?

- Infections before or after ZOLGENSMA infusion can lead to more serious complications. Contact the patient's doctor immediately if you see any signs of a possible infection such as coughing, wheezing, sneezing, runny nose, sore throat, or fever.
- Decreased platelet counts could occur following infusion with ZOLGENSMA. Seek immediate medical attention if the patient experiences unexpected bleeding or bruising.
- Thrombotic microangiopathy (TMA) has been reported to occur approximately one week after ZOLGENSMA infusion. Caregivers should seek immediate medical attention if the patient experiences any signs or symptoms of TMA, such as unexpected bruising or bleeding, seizures, or decreased urine output.

What do I need to know about vaccinations and ZOLGENSMA?

- Talk with the patient's doctor to decide if adjustments to the vaccination schedule are needed to accommodate treatment with a corticosteroid.
- Protection against respiratory syncytial virus (RSV) is recommended.

Do I need to take precautions with the patient's bodily waste?

Temporarily, small amounts of ZOLGENSMA may be found in the patient's stool. Use good hand hygiene when coming into direct contact with bodily waste for 1 month after infusion with ZOLGENSMA. Disposable diapers should be sealed in disposable trash bags and thrown out with regular trash.

What are the possible or likely side effects of ZOLGENSMA?

The most common side effects that occurred in patients treated with ZOLGENSMA were elevated liver enzymes and vomiting.

The safety information provided here is not comprehensive. Talk to the patient's doctor about any side effects that bother the patient or that don't go away.

You are encouraged to report suspected side effects by contacting the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch, or Novartis Gene Therapies, Inc. at 833-828-3947.

Please see accompanying Full Prescribing Information.

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