UTAH MEDICAID PHARMACY PRIOR AUTHORIZATION REQUEST FORM

Zolgensma (onasemnogene abeparvovec-xioi) and Itvisma (onasemnogene abeparvovec-brve)

Member and Medication Information * indicates required field	
*Member ID:	*Member Name:
*DOB:	*Weight:
*Medication Name/ Strength:	
☐ Do Not Substitute. Authorizations will be processed for the preferred Generic/Brand equivalent unless specified.	
*Directions for use:	
Provider Information * indicates required field	
*Requesting Provider Name:	*Requesting Prescriber NPI:
Address:	
*Contact Person:	*Office Phone:
*Office Fax:	*Office Email:
Medically Billed Information * indicates required field for all medically billed products	
*Diagnosis Code:	*HCPCS Code:
*Dosing Frequency:	*HCPCS Units per Dose:
Servicing Provider Name:	NPI:
Servicing Provider Address:	
Facility/Clinic Name:	NPI:
Facility/Clinic Address:	
Fax form and relevant documentation including: laboratory results, chart notes and/or updated provider letter to Pharmacy PA at **855-828-4992**, to prevent processing delays.	

Criteria for Approval: (*All* of the following criteria must be met)

1. Is the medication being prescribed by or in consultation with a provider specializing in the treatment of spinal muscular atrophy (SMA)? ❑ **Yes** ❑ **No**
2. Has the provider submitted a baseline anti-AAV9 antibody titer result and attest to monitor the anti-AAV9 antibody level after the treatment? ❑ **Yes** ❑ **No**
3. Does the provider attest that the patient does **NOT** have advanced SMA (e.g., complete paralysis of limbs, permanent ventilator dependence)? ❑ **Yes** ❑ **No**
4. Has the provider performed an assessment of motor function development milestones using age appropriate screening tools? ❑ **Yes** ❑ **No**
5. Does the provider attest that the following tests will be performed at baseline and monitored after treatment until results return to baseline or as clinically appropriate? ❑ **Yes** ❑ **No**
   - ☐ Liver Function (clinical exam, AST, ALT, total bilirubin, prothrombin time), Creatinine, Complete Blood Count and Troponin-I

- ☐ Overall baseline health status (hydration and nutritional status, active or recent infections, respiratory status, etc.)
- ☐ Up-to-date vaccination status

6. Does the provider attest that the patient will receive systemic corticosteroid before and after the treatment? ❑ **Yes** ❑ **No**
7. Does the provider attest that the patient has **NOT** received Zolgensma or Itvisma before? ❑ **Yes** ❑ **No**
8. Does the provider attest that the patient will **NOT** receive routine concomitant SMA modifying therapy (e.g., Spinraza (nusinersen), Evrysdi (risdiplam)) following administration of Zolgensma or Itvisma? ❑ **Yes** ❑ **No**

*Prior authorizations for SMA modifying therapy will be terminated upon confirmed administration of Zolgensma or Itvisma. Future use of SMA modifying therapy will only be considered if a post Zolgensma or Itvisma administration clinical assessment documents a suboptimal therapeutic response or a decline in motor function requiring supplemental treatment.

Additional Criteria for Zolgensma:

9. Does the patient have a documented diagnosis of Spinal Muscular Atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN 1) gene? ❑ **Yes** ❑ **No**
10. If this is for a premature neonate, will the patient reach full-term gestational age by the time of Zolgensma administration? ❑ **Yes** ❑ **No**
11. Will the patient be under 2 years of age on the date of treatment? ❑ **Yes** ❑ **No**
12. Does the patient weigh less than 21 kg? Current weight: _____ ❑ **Yes** ❑ **No**

Additional Criteria for Itvisma:

13. Does the patient have a documented diagnosis of Spinal Muscular Atrophy (SMA) with mutations in the survival motor neuron 1 (SMN 1) gene? ❑ **Yes** ❑ **No**
14. Will the patient be 2 years of age or older on the date of treatment? ❑ **Yes** ❑ **No**
15. Will Itvisma be administered intrathecally by a healthcare professional experienced in performing lumbar punctures? ❑ **Yes** ❑ **No**

Initial Authorization: One (1) dose per lifetime

Reauthorization: None

Note:

- ❖ Acute serious liver injury and elevated aminotransferases can occur with Zolgensma and Itvisma. Assess liver function by clinical examination and laboratory testing prior to administration. Administer systemic corticosteroid before and after giving Zolgenma and Itvisma. Continue to monitor liver function for at least 3 months after administration, and at other times as clinically indicated.
- ❖ Provider shall review and submit additional Ultra High Cost Drug Forms below at: https://medicaid.utah.gov/pharmacy/resource-library/
  - ➢ UHCD Written Claim of Business Confidentiality Form
  - ➢ Ultra High Cost Drug Invoice Submission Form

PROVIDER CERTIFICATION

I hereby certify this treatment is indicated, necessary and meets the guidelines for use.

_____ _____

Prescriber's Signature Date

For ADA accommodation or assistance completing this form, please call us at 801-538-6155.