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 WEB: [DSS Medicaid Prior Authorizations](#) | EMAIL : DSSMedicaidpa@state.sd.us

ITVISMA PRIOR AUTHORIZATION REQUEST FORM

This form **MUST BE** submitted with medical records to support services

Date:		
RECEIPIENT INFORMATION		
Medicaid ID:	Date of Birth:	Sex: M F
Last Name:		First Name:
GENERAL INFORMATION		
First Date of Service:		Last Date of Service:
Primary Diagnosis Code:		HCPC Code:
Drug Name:		Dose & Frequency:
Hospitalizations/Treatments/Medications Used in the last 6 months:		
POINT OF CONTACT		
Name and Title:		
Email:	Phone:	Fax:
<small><i>Note: The point of contact is the individual completing the PA and would be the contact for questions SD Medicaid may have regarding the PA. The determination notice will be sent to the listed point of contact.</i></small>		
REFERRING PROVIDER INFORMATION		
Name:		
NPI #:		Taxonomy:
Phone:		Fax:
SERVICING PROVIDER INFORMATION		
Name:		
Address:		
NPI #:		Taxonomy:
Phone:		Fax:

CRITERIA		
Medical records to support use of product are submitted		
Initial Therapy (check one)	Yes	No
	Therapy is prescribed by a board-certified pediatric neurologist with expertise in the treatment of SMA	
	Individual has an SMA diagnosis with submitted documentation (e.g., chart notes, laboratory values) confirming the mutation or deletion of genes in chromosome 5q resulting in homozygous gene deletion or mutation of SMN1 gene (e.g., homozygous deletion of exon 7 at locus 5q13)	
	Individual has ≤ 3 copies of the SMN2 gene	
	Individual is ≥ 2 to < 18 years of age	
	For use in a neonatal patient born prematurely, the full-term gestational age has been reached	
	Individual can sit independently but cannot stand or walk independently and does not have complete paralysis of limbs	
	Individual does not have severe contractures or scoliosis that would interfere with ability to receive intrathecal dosing	
	Individual is not dependent on either of the following: <ul style="list-style-type: none"> • Invasive ventilation or tracheostomy • Use of non-invasive ventilation beyond use for naps and nighttime sleep 	
	Individual is not unable to receive nutrition through normal means (i.e. reliant on a gastric feeding tube for the majority of feedings)	
	Individual is not to receive routine concomitant SMN modifying therapy [e.g., Spinraza (nusinersen), Evrysdi (risdiplam)]. Patient's medical record will be reviewed and any current authorizations for SMN modifying therapy will be terminated upon Itvisma approval; patient access to subsequent SMN modifying therapy will be assessed according to respective coverage policy of concomitant agent	
	Individual does not have an elevated anti-adenovirus serotype 9 (anti-AAV9) antibody titer above 1:50	
	Screening has been done within the last 6 months and documentation is provided indicating that the individual is negative for the following active diseases: HIV, Hepatitis B, and Hepatitis C	
	Individual does not have clinically significant abnormal laboratory values (defined as gamma-glutamyl transferase, ALT, AST or total bilirubin $> 2x$ upper limit of normal, creatinine ≥ 1.0 mg/dL, hemoglobin < 8 or > 18 g/dL, WBC $> 20,000$ per cmm)	
	Baseline functional status is documented by one of the following: <ul style="list-style-type: none"> • Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorder score (CHOP INTEND) • Hammersmith Infant Neurological Exam (HINE) • Hammersmith Functional Motor Scale Expanded (HFMSE) 	
	If female, documentation of negative pregnancy test must be submitted prior to therapy	
	Male and female members of reproductive potential must use an effective method of contraception at start of treatment and at least 6 months following Itvisma administration	
	Individual has never received Itvisma or Zolgensma treatment in their lifetime	
PHYSICIAN SIGNATURE – PROVIDER ONLY		
This form <u>must be</u> signed by a provider		
	I certify that the information given in this form is a true and accurate medical indication for the required product	
Name & Title (Printed):		Specialty:
Signature:		