



FROM



Telephone: (800) 514-0083 option 2

Fax: (866) 374-1579

Onasemnogene abeparvovec (Zolgensma)

PDAC Drug Review Form

The information below can be completed by the Health Plan and/or Centene Pharmacy Services (CPS) staff

## Patient Information

*Last Name:	*First Name:	Middle:	*DOB: / /
Daytime Phone:		Evening Phone:	*Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female

## Insurance Information

*Primary Insurance (Health Plan Name and State)	*ID #:
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## Physician Information

*Name:	*Specialty:	*Phone #:
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## Procedural Hospital

*Hospital Name:
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## Primary Diagnosis

*ICD-10 Code:
<input type="checkbox"/> Spinal muscular atrophy (SMA) type 1 <input type="checkbox"/> Other: _____

## Prescription Information

MEDICATION	STRENGTH	*DIRECTIONS	QUANTITY	REFILLS
Zolgensma (Onasemnogene abeparvovec)				

## Clinical Information

\*\*\*\*\* Please submit supporting clinical documentation \*\*\*\*\*

\* THERAPY Start Date: \_\_\_\_\_

- Is therapy prescribed by or in consultation with a neurologist? ☐ Yes ☐ No
- Did patient have onset of symptoms prior to 6 months of age? ☐ Yes ☐ No
- Does genetic testing quantifying number of copies of survival motor neuron 2 (SMN2) gene confirm any of the following? ☐ Yes **\*\*Mark all that apply\*\*** ☐ No
  - ☐ 1, 2, or 3 copies of SMN2 gene
  - ☐ 4 copies of SMN2 gene, determined by a quantitative assay that is able to distinguish between four SMN2 gene copies and five or more SMN2 gene copies
- Does genetic testing confirm any of the following? ☐ Yes **\*\*Mark all that apply\*\*** ☐ No
  - ☐ Homozygous deletions of SMN1 gene (e.g., absence of the SMN1 gene)
  - ☐ Homozygous mutation in the SMN1 gene (e.g., biallelic mutations of exon 7)
  - ☐ Compound heterozygous mutation in the SMN1 gene (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2])
- Please document the following patient information:
  - Patient's weight: \_\_\_\_\_ kg
  - Baseline Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorder (CHOP-INTEND) score: \_\_\_\_\_
  - Baseline Hammersmith Infant Neurological Examination (HINE) motor milestone score: \_\_\_\_\_
  - Baseline laboratory tests demonstrating Anti-AAV9 antibody titers  $\leq 1:50$  as determined by ELISA binding immunoassay: \_\_\_\_\_
  - Baseline liver function test: \_\_\_\_\_, platelet counts: \_\_\_\_\_, troponin-I: \_\_\_\_\_
- Does patient have advanced SMA (e.g., complete paralysis of limbs, permanent ventilator dependence for 16 or more hours per day, tracheostomy, non-invasive ventilation beyond the use for sleep)? ☐ Yes ☐ No
- Has patient been previously treated with Zolgensma? ☐ Yes ☐ No
- Is Zolgensma prescribed concurrently with Spinraza or Evrysdi? ☐ Yes ☐ No
- Is patient currently on Spinraza? ☐ Yes **\*\*Must submit documentation & mark all that apply\*\*** ☐ No
  - ☐ Evidence of clinical deterioration upon completion of all loading doses of Spinraza (e.g., sustained decrease in CHOP-INTEND score over a period of 3 to 6 months) upon completion of all loading doses of Spinraza
  - ☐ Spinraza is being used as a bridge therapy to Zolgensma
  - ☐ Provider attestation of clinical deterioration and Spinraza discontinuation
- Is patient currently on Evrysdi? ☐ Yes **\*\*Must submit documentation & mark all that apply\*\*** ☐ No
  - ☐ Evidence of clinical deterioration (e.g., sustained decrease in CHOP-INTEND score over a period of 3 to 6 months)
  - ☐ Evrysdi is being used as a bridge therapy to Zolgensma
  - ☐ Provider attestation of clinical deterioration and Evrysdi discontinuation
- Does patient have an active viral infection? ☐ Yes **\*\*Mark all that apply\*\*** ☐ No



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- ☐ HIV ☐ Hepatitis B ☐ Hepatitis C ☐ Zika ☐ Upper/lower respiratory tract infection  
☐ Non-respiratory tract infection ☐ Other: \_\_\_\_\_

12. How many Zolgensma infusions has patient received? ☐ 0 ☐ ≥ 1

Please continue to page 2.

Patient Name: \_\_\_\_\_ DOB: \_\_\_\_\_

**Complete this section ONLY for indications other than SMA:**13. Has patient tried and failed, or is contraindicated to, accepted standards of care? ☐ Yes ☐ No

\*\*If yes, submit documentation and answer the following:\*\*

- a. Please list all previous therapies: \_\_\_\_\_  
b. Was patient adherent to previously tried therapies? ☐ Yes ☐ No ☐ No, patient intolerant to drug

**Information**

\*Number:

\*Date of Request:

\*HCPCS Code:

\*Decision Due Date:

\*Line of Business:

- ☐ Commercial ☐ Health Insurance Marketplace  
☐ Medicaid ☐ Medicare

\*Benefit:

- ☐ Medical ☐ Pharmacy

## \* Choose one criteria option below based on line of business:

**Medicare Criteria Only:**

- ☐ Medicare Local Coverage Decision (LCD) specific for your region  
Please include policy of link to LCD, followed by any applicable Medicare Part B step therapy requirements in MCPB.ST.00.
- ☐ Medicare National Coverage Decision (NCD).  
Please include policy of link to NCD, followed by any applicable Medicare Part B step therapy requirements in MCPB.ST.00.

**Medicaid, Commercial, Exchange (Ambetter) Criteria:**

- ☐ Centene Policy [CP.PHAR.421 Onasemnogene Abeparvovec (Zolgensma)]

Date Policy last reviewed/approved by plan (we want to be sure we are using the version approved by your plan):

\_\_\_\_\_

**OR**

- ☐ State or Health Plan Specific (please include policy)