

**SOUTH DAKOTA MEDICAID  
PRIOR AUTHORIZATION CRITERIA**

*Physician Administered Drugs, Vaccines, and Immunizations*

**Onasemnogene Apeparvovec (Zolgensma) – PA Criteria**

HCPC: J3399

Zolgensma is a recombinant adeno-associated virus vector-based gene therapy that is indicated for the treatment of spinal muscular atrophy (SMA) in infants and children <2 years of age. It is covered by South Dakota Medicaid following prior authorization when the following criteria are met:

\*\* All requests under this policy require SD medical director review **in addition** to meeting specified criteria below \*\*

• **Initial Therapy (must meet all):**

- 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 **one** of the following:
  - Homozygous gene deletion or mutation of SMN1 gene (e.g., homozygous deletion of exon 7 at locus 5q13)
  - Compound heterozygous mutation of SMN1 gene (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2])
- Individual has ≤3 copies of the SMN2 gene
- Individual is <2 years of age
- For use in a neonatal patient born prematurely, the full-term gestational age has been reached
- Individual is not dependent on **either** of the following:
  - Invasive ventilation or tracheostomy
  - Use of non-invasive ventilation beyond use for naps and nighttime sleep
- 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 Zolgensma 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-adeno-associated virus serotype 9 (anti-AAV9) antibody titer above 1:50
- Individual has LFTs less than 2X ULN determined by a certified lab
- Baseline functional status is documented by **one** of the following:
  - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorder score (CHOP INTEND)
  - Hammersmith Infant Neurological Exam (HINE)
  - Hammersmith Functional Motor Scale Expanded (HFMSE)
- Individual has never received Zolgensma treatment in their lifetime
- Approval duration: one dose or until individual reaches 2 years of age, whichever is first

• **Continuation of Therapy:** not authorized

Zolgensma is not covered for:

- The treatment of patients diagnosed by newborn screening who have more than 3 copies of the SMN2 gene.
- The treatment of symptomatic later-onset SMA older than 2 years of age
- SMA without chromosome 5q mutations or deletions.
- The routine combination treatment of SMA with concomitant SMN modifying therapy