Reference number(s)
C16942-A

CAREFIRST: ZOLGENSMA

Client Requested: The intent of the criteria is to ensure that patients follow selection elements as established by CareFirst.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- Diagnosis of spinal muscular atrophy confirmed by genetic testing demonstrating bi-allelic mutations in the survival motor neuron 1 (SMN1) gene as stated below:
  - deletion of both copies of the SMN1 gene
    OR
  - compound heterozygous mutations of the SMN1 gene (defined below):
    - pathogenic variant(s) in both copies of the SMN1 gene.
    - pathogenic variant in 1 copy and deletion of the second copy of the SMN1 gene.

  AND
- Documentation of a genetic test confirms no more than 4 copies of the SMN2 gene.
  AND
- The patient is less than 2 years of age at the time of infusion of onasemnogene abeparvovec- xioi
  AND
- Documentation of baseline laboratory assessments such as AST, ALT, total bilirubin, and prothrombin time.
  AND
- The patient does not have advanced spinal muscular atrophy (e.g., complete paralysis of limbs, permanent ventilator dependence).
  AND
- Baseline anti-adeno-associated virus serotype 9 (AAV9) antibody titers < 1:50.
  AND
- Prescribed by a neurologist with expertise in treating spinal muscular atrophy.
  AND
- Dosing Limits: 1 injection per lifetime

  Repeat treatment or ante-partum use of onasemnogene abeparvovec-xioi is considered **investigational**.
  Onasemnogene abeparvovec-xioi is considered **investigational** for all other indications.
  Concurrent use of onasemnogene abeparvovec-xioi with nusinersen and/or risdiplam is considered **investigational.**
  Use of nusinersen and/or risdiplam after administration of onasemnogene abeparvovec-xioi is considered **investigational.**

DOCUMENT HISTORY

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