



STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES



Office of Pharmacy Service
Prior Authorization Criteria

Zolgensma®
Effective 07/01/2020
Billed under J3399

[Prior Authorization Request Form](#)

Zolgensma is the first gene therapy approved to treat children less than 2 years of age with spinal muscular atrophy (SMA).

CRITERIA FOR APPROVAL:

1. The patient has a genetically confirmed diagnosis of spinal muscular atrophy, with documentation of bi-allelic mutations in the survival motor neuron 1 (SMN1) gene; **AND**
2. The patient is less than 2 years of age; **AND**
3. The patient has reached full-term gestational age; **AND**
4. The medication is prescribed by or in consultation with a neurologist or a neuromuscular specialist in the treatment of spinal muscular atrophy; **AND**
5. The patient has an anti-adenovirus 9 (AAV9) antibody titer $\leq 1:50$ as determined by Enzyme-linked Immunosorbent Assay (ELISA) binding immunoassay; **AND**
6. Baseline liver function tests, platelet counts, and troponin-1 have been performed and will continue to be assessed after treatment until they return to baseline or are unremarkable; **AND**
7. The patient does not have advanced SMA (such as complete paralysis of limbs or permanent ventilator dependence*); **AND**
8. The patient has not previously received Zolgensma; **AND**
9. The patient does not have any pre-existing hepatic insufficiency; **AND**
10. The patient does not have an active viral infection; **AND**
11. The medication will not be used in combination with nusinersen (Spinraza).



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Prior authorization approval will be limited to a ONE-TIME infusion based on a weight appropriate dose and cannot be reauthorized.

Additional Information:

*Permanent ventilator dependence is defined as requiring invasive ventilation (tracheostomy), or respiratory assistance for 16 or more hours per day (including noninvasive ventilatory support) continuously for 14 or more days in the absence of an acute reversible illness, excluding perioperative ventilation.

References

- 1.) Lexi-Comp Clinical Application 4/28/2020
- 2.) Zolgensma Package Insert