STATE OF WEST VIRGINIA
DEPARTMENT OF HUMAN SERVICES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Services
Prior Authorization Criteria

Zolgensma® (onasemnogene abeparvovec-xioi)
Billed under: J3399

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

Initial authorization requires review by the Medical Director and may be approved when all of the following criteria is met:

1. Must be prescribed by, or in documented consultation with, a Neurologist or a Neuromuscular Specialist in the treatment of spinal muscular atrophy; **AND**

2. The patient has a genetically confirmed diagnosis of spinal muscular atrophy (SMA), with documentation of bi-allelic mutations in the survival motor neuron 1 (SMN1) gene; **AND**

3. The patient is less than 2 years of age; **AND**

4. The patient has reached full-term gestational age; **AND**

5. The patient has an anti-adeno-associated virus 9 (AAV9) antibody titer ≤ 1:50 as determined by Enzyme-Linked Immunosorbent Assay (ELISA) binding immunoassay; **AND**

6. Baseline liver function tests, creatinine, complete blood count (including hemoglobin and platelet count), and troponin-I 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**

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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®).

*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.

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

Additional Requirements:

One day prior to Zolgensma infusion, begin administration of systemic corticosteroids equivalent to oral prednisolone at 1 mg per kg of body weight per day (mg/kg/day) for a total of 30 days.

References:

Government Agency, Medical Society, and Other Authoritative Publications:

1. Lexi-Comp Clinical Application (Accessed 4/28/2020)
2. Zolgensma [package insert]. Bannockburn, IL: Novartis Gene Therapies, Inc.; 2023. https://www.novartis.com/us-en/sites/novartis_us/files/zolgensma.pdf (Accessed 5/3/2024)

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member according to BMS coverage and policy guidelines.