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ONASEMNOGENE ABEPARVOVEC-XIOI (ZOLGENSMA®) (MP-2.368)

Preauthorization Request

(Preauthorization is not a guarantee of payment)

SECTION I – General Information

Initial start date of therapy: / / Anticipated date of infusion: / /	Fax completed form to: **1-866-805-4150 toll free**

SECTION II – Member Information

Member Name:	Member ID:	Member DOB: / /

Plan Type: ☐ CHIP (aka Capital Cares 4Kids) ☐ Traditional ☐ Comprehensive ☐ PPO ☐ POS ☐ KHPC
☐ Special Care ☐ BlueJourney HMO ☐ BlueJourney PPO ☐ BlueJourney Alliance

SECTION III – Provider Information Required

Requesting Provider Name: **Address**:	**Requesting Provider CBC #**_____ **NPI #** _____
Telephone #:	Fax #:
Office Contact Name:	Office Contact Telephone #:

Place of Service: ☐ MD Office ☐ Name/Address of the Hospital/Clinic/Home Health (List below)

SECTION IV – Preauthorization Requirements and Clinical Criteria

Prescribed in consultation with a neurologist? ☐ Yes ☐ No

Diagnosis:_____ **HCPC Code:** _____ **Other HCPC Code:** _____
☐ Spinal muscular atrophy (SMA): Diagnosis Code: _____
☐ Other diagnosis: _____ Diagnosis code_____

1. Is the patient less than 2 years of age? ☐ Yes ☐ No
2. Is there documentation of bi-allelic mutations in the survival motor neuron 1 (SMN1) gene as confirmed by one of the following?
   a. Deletion of both SMN1 gene copies ☐ Yes ☐ No
   b. Pathogenic variants in one copy and deletion of the second copy ☐ Yes ☐ No or
   c. Pathogenic variants in both copies of the gene ☐ Yes ☐ No
3. Does the patient have less than or equal to two copies of the SMN2 gene?
   ☐ Yes ☐ No
4. Does the patient have any of the following laboratory abnormalities?
   a. Liver function levels (hepatic aminotransferases [AST and ALT] greater than or equal to 2 times upper limit of normal) ☐ Yes ☐ No
   b. Baseline anti-AAV9 antibodies greater than 1:50 ☐ Yes ☐ No
   c. Platelet count less than 150,000µL ☐ Yes ☐ No
   d. Gamma-glutamyl transferase (GGT) greater than 144U/L (3 times the upper limit of normal) ☐ Yes ☐ No

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e. Bilirubin greater than or equal to 3.0 mg/dL ☐ Yes ☐ No
f. Creatinine greater than or equal to 1.8 mg/dL ☐ Yes ☐ No

5. Will the patient have their liver function monitored for at least three months after infusion?
   ☐ Yes ☐ No
6. Is the prescriber a specialist in the area of the patient's diagnosis (e.g., neurologist) or has the prescriber consulted with a specialist in the area of the patient's diagnosis?
   ☐ Yes ☐ No
7. Will the patient receive systemic corticosteroid before and after onasemnogene abeparvovec-xioi (Zolgensma®) infusion?
   ☐ Yes ☐ No
8. Has the patient previously been administered onasemnogene abeparvovec-xioi (Zolgensma®)?
   ☐ Yes ☐ No
9. Does the patient have advanced SMA (e.g., complete paralysis of limbs, permanent ventilator dependence [defined as invasive ventilation (tracheostomy), or respiratory assistance for 16 or more hours per day (including noninvasive ventilatory support) continuously for 14 or more days in absence of an acute reversible illness, excluding perioperative ventilation])?
   ☐ Yes ☐ No
10. Is the patient currently being treated with nusinersen (Spinraza®)?
    ☐ Yes ☐ No
11. If yes, will the patient discontinue nusinersen (Spinraza®) prior to starting the requested agent?
    ☐ Yes ☐ No
12. Does the patient have any FDA labeled contraindications to the requested agent?
    ☐ Yes ☐ No.
13. Is the requested dose within FDA labeled dosing for the requested indication?
    ☐ Yes ☐ No

Length of Approval: Once per lifetime

Dosing Information

Route of administration ☐ Intravenous Dose:

SECTION V – Required Physician Signature

Physician's Signature	Date: / /

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