SENTARA COMMUNITY PLAN
(MEDICAID)

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-305-2331**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

Drug Requested: Zolgensma® (onasemnogene abeparvovec-xioi) **IV (Medical) (J3399)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Approval Length: 1 (one) dose per lifetime – may not be renewed
Quantity Limit: 1 billable unit (1 treatment of up to 1.2 x 1014 vector genomes)

❑ Member is at least 2 years of age or older

❑ Member has not received prior treatment with spinal muscular atrophy (SMA) gene therapy (e.g., onasemnogene abeparvovec-xioi [Zolgensma], etc.)

(Continued on next page)

- ❑ Member has a diagnosis of 5q spinal muscular atrophy confirmed by either bi-allelic deletion or dysfunctional point mutation of the survival motor neuron 1 (SMN1) gene; **AND**
- ❑ Member must have SMA phenotype 1 or 2 confirmed by one or more of the following:
  - ❑ 1 to 2 copies of the SMN2 gene; **OR**
  - ❑ 3 or 4 copies of the SMN2 gene in the absence of the c.859G>C single base substitution modification in exon 7
- ❑ Member must have a baseline anti-AAV9 antibody titer of ≤ 1:50 measured by ELISA
- ❑ Baseline liver function will be assessed prior to initiating therapy and will continue to be monitored for at least 3 months after therapy
- ❑ Used concomitantly with systemic corticosteroids
- ❑ Member does not have advanced disease (complete limb paralysis, permanent ventilation support, etc.)
- ❑ Will not be used in combination with other SMN-targeting agents for SMA (e.g., nusinersen, risdiplam, onasemnogene abeparvovec-xioi, etc.).

ADDITIONAL INFORMATION:

Is this for pre-symptomatic treatment?

❑ Yes ❑ No

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee: 7/18/2019**
REVISED/UPDATED/REFORMATTED: ~~9/29/2019; 10/29/2019; 9/29/2020; 10/16/2020;10/21/2021; 10/25/2023; 6/20/2024;~~ **4/29/2026**