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

- ❑ Prescribed by a Pediatric Neuromuscular Neurologist with expertise in SMA
- ❑ Individual has a diagnosis of 5q spinal muscular atrophy confirmed by either bi-allelic deletion or dysfunctional point mutation of the SMN1 gene; AND
- ❑ Individual must have SMA phenotype 1 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

(Continued on next page)

- ❑ Individual is less than 24 months of age
- ❑ Individual is not ventilator-dependent, defined as requiring invasive ventilation (tracheostomy) or respiratory assistance for 16 or more hours per day (including noninvasive ventilator support) continuously for 21 or more days in the absence of an acute reversible event
- ❑ Individual has baseline anti-AAV9 antibody titer of ≤ 1:50 measured by ELISA
- ❑ Individual has LFTs less than 2X the upper limit of normal determined by certified laboratory
- ❑ Individual has received **NO** treatment with immunosuppressive therapy in the 3 months prior to starting Zolgensma treatment (e.g., corticosteroids, cyclosporine, tacrolimus, methotrexate, cyclophosphamide, intravenous immunoglobulin, rituximab)
- ❑ Individual does **NOT** have advanced disease (e.g., complete limb paralysis, permanent ventilation support)
- ❑ Individual does **NOT** have symptoms of active viral infection
- ❑ Individual does **NOT** have concomitant illness that may create unnecessary risks for gene transfer
- ❑ Individual has had **NO** prior treatment with Zolgensma
- ❑ The member will **NOT** receive the requested treatment in combination with Spinraza (nusinersen) or Evrysdi (risdiplam)

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 – Proprium Rx

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.****