

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) (J-3399)

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: _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight: _____ Date: _____

- 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

- Prescription is by a Pediatric Neuromuscular Neurologist with expertise in SMA
 Yes No
- Individual has a diagnosis of 5q spinal muscular atrophy confirmed by either bi-allelic deletion or dysfunctional point mutation of the SMN1 gene, with 1 - 3 copies of SMN2
 Yes No

(Continued on next page)

- 3. Individual is less than 24 months of age Yes No
- 4. 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
- 5. Yes No
- 6. Individual has baseline anti-AAV9 antibody titer of $\leq 1:50$ measured by ELISA Yes No
- 7. Individual has LFTs less than 2X ULN determined by certified laboratory Yes No
- 8. 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) Yes No
- 9. Individual does **NOT** have advanced disease (e.g., complete limb paralysis, permanent ventilation support) Yes No
- 10. Individual does **NOT** have symptoms of active viral infection Yes No
- 11. Individual does **NOT** have concomitant illness that may create unnecessary risks for gene transfer Yes No
- 12. Individual has had **NO** prior treatment with Zolgensma. Yes No
- 13. Is this for pre-symptomatic treatment? Yes No

Medication being provided by (check box below that applies):

- Location/site of drug administration: _____
NPI or DEA # of administering location: _____

OR

- Specialty Pharmacy - PropriumRx

For urgent reviews: Practitioner should call Sentara Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara'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.