

SENTARA HEALTH PLANS

PHARMACY 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 1-800-750-9692.** 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 may be delayed.

Drug Requested: Evrysdi® (risdiplam) (Pharmacy)
Evrysdi 0.75 mg/mL oral solution – 60 mg glass bottle (NDC: 50242-0175-**))

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: _____

Recommended Dosage:

Age and Body Weight	Recommended Daily Dosage
Less than 2 months of age	0.15 mg/kg
2 months to less than 2 years of age	0.2 mg/kg
2 years of age and older weighing less than 20 kg	0.25 mg/kg
2 years of age and older weighing 20 kg or more	5 mg

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.

Initial Authorization: 6 months

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Concomitant use of Zolgensma[®] (onasemnogene abeparvovec-xioi) or Spinraza[®] (nusinersen) with Evrysdi[®] is considered investigational and not covered.

- Has member tried Zolgensma[®]? Yes No
 If yes, please provide date of therapy: _____

AND

- Member must **NOT** have previously received treatment with SMA gene therapy (i.e., onasemnogene abeparvovec-xioi)

AND

- Member will **NOT** use in combination with other agents for SMA (e.g., onasemnogene abeparvovec, nusinersen)

AND

- Member does **NOT** have respiratory insufficiency, defined by the medical necessity for invasive or non-invasive ventilation for greater than 6 hours during a 24-hour period, at screening ([submit chart notes documenting ventilation use for documentation](#))

AND

- Member retains meaningful voluntary motor function (e.g., manipulate objects using upper extremities, ambulate)

AND

- Member must have a diagnosis of 5q spinal muscular atrophy confirmed by either homozygous deletion of the SMN1 gene or dysfunctional mutation of the SMN1 gene **AND**

- Member must have **ONE** of the following SMA phenotypes/Member has been identified as SMA Type 1, 2 or 3 ([submit lab documentation showing the number of SMN2 copies](#)):

- SMA I confirmed by **ONE** of the following ([submit labs showing the number of SMN2 copies](#)):

- Member must have 1-2 copies of the SMN2 gene
 Member has 3 copies of the SMN2 gene in the absence of the c.859G>C single base substitution modification in exon 7

- SMA II with symptomatic disease (i.e., impaired motor function and/or delayed motor milestones)

- SMA III with symptomatic disease (i.e., impaired motor function and/or delayed motor milestones)

AND

- If applicable: Member is 2 years of age or older **AND** is ambulant defined as being able to walk unassisted for > 10 m Yes No

AND

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- Submit completed baseline movement assessments with **ONE** of the following:
 - Motor function/milestone: _____/32
 - Hammersmith Infant Neurologic Exam (HINE): _____/68
 - Hammersmith Functional Motor Scale for SMA (HFMS): _____/66
 - Bayley Scales of Infant and Toddler development Third Ed. (BSID-III): _____

AND

- Baseline assessment of **ONE** of the following:
 - Number of hospitalizations in the last 12 months: _____
 - Number of antibiotic therapies for respiratory infection used in the last 12 months: _____
 - Current respiratory function test (e.g., forced vital capacity (FVC)): _____

Reauthorization: 12 months. All criteria that apply must be checked for approval. To support each line checked, all documentation (lab results, diagnostics, and/or chart notes) must be provided or request may be denied.

- Continuation of treatment with **Evrysdi® beyond twelve (12) months** after initiation of therapy **AND every twelve (12) months thereafter** is considered medically necessary for the treatment of spinal muscular atrophy (SMA) when individuals meet **ALL** of the following:
 - Member continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy) (**NO** concomitant Zolgensma or Spinraza)
 - Member has shown an improvement or no decrease from baseline score [**a decline from the baseline (6 months) over a 12-month evaluation would be considered not medically necessary**]; **one (1)** assessment below will be reviewed from previous baseline:
 - Number of hospitalizations in the last 6 months: _____
 - Number of antibiotic therapies for respiratory infection in the last 6 months: _____
 - Current respiratory function test [e.g., forced vital capacity (FVC)]: _____

AND

- Documentation of movement assessment, obtained within 30 days of request must be provided or request may be denied:
 - Motor function/milestone: _____/32
 - Hammersmith Infant Neurologic Exam (HINE): _____/68
 - Hammersmith Functional Motor Scale for SMA (HFMS): _____/66
 - Bayley Scales of Infant and Toddler development Third Ed. (BSID-III): _____

AND

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- Permanent ventilation defined as tracheostomy or ≥ 16 hours ventilator support per day would be considered a failure of Evrysdi[®] and will not be approved for continuation. Does member require permanent ventilation as defined above? Yes No

AND

- Member has experienced an absence of unacceptable toxicity from the medication which would preclude safe administration of the drug (e.g., hypersensitivity reactions, severe diarrhea)

AND

- Stable or increased member weight (for members without a gastrostomy tube)

Medication being provided by a Specialty Pharmacy - PropriumRx

Not all drugs may be covered under every Plan.

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

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.