

# AvMed

## 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 1-305-671-0200.** No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can 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 AvMed #: \_\_\_\_\_ 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<sup>®</sup> (onasemnogene abeparvovec-xioi) or Spinraza<sup>®</sup> (nusinersen) with Evrysdi<sup>®</sup> is considered investigational and not covered.**

- Has member tried Zolgensma<sup>®</sup>?  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  $\geq 16$  hours ventilator support per day would be considered a failure of Evrysdi<sup>®</sup> 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 member's 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.\**