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)**

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:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

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

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

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

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 – Proprium Rx

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.