



## Prior Authorization Criteria

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### **Evrysdi® (risdiplam) PA Criteria**

Evrysdi is a survival of motor neuron 2 (SMN2) splicing modifier indicated for the treatment of spinal muscular atrophy (SMA) in patients 2 months of age and older.

**Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.**

#### ***Initial Authorization: 6 months***

Yes  No Diagnosis of SMA;

***AND***

Yes  No Age  $\geq$  2 months

***AND***

Yes  No Member is symptomatic

***AND***

Yes  No Genetic testing quantifying number of copies of SMN2 gene  $\geq$  1 but  $\leq$  4

***AND***

Genetic testing confirms the presence of one of the following (a, b, or c)

- a. Homozygous deletions of SMN1 gene (e.g., absence of the SMN1 gene);
- b. Homozygous mutation in the SMN1 gene (e.g., biallelic mutations of exon 7);
- c. Compound heterozygous mutation in the SMN1 gene [e.g., deletion of SMN1 exon 7 (allele 1) and mutation of SMN1 (allele 2)];

***AND***

Yes  No Prescribed by or in consultation with a neurologist

***AND***

Documentation of one of the following baseline scores (a or b):

- a. For age  $<$  2 years: Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorder (CHOP-INTEND) score or Hammersmith Infant Neurological Examination (HINE) Section 2 motor milestone score;

- b. For age  $\geq$  2 years: Hammersmith functional motor scale expanded (HFMSE) score, Revised Hammersmith Scale (RHS), Upper Limb Module (ULM), Revised Upper Limb Module (RULM), or 6-Minute Walk Test (6MWT)

**AND**

Yes  No Member does not require tracheostomy or invasive ventilation.

**AND**

Evrysdi is not prescribed concurrently with Spinraza® and/or Zolgensma®;

**AND**

If the member is currently on Spinraza, documentation of prescriber attestation of Spinraza discontinuation;

**AND**

Request meets one of the following (a, b or c):

- a. If 2 months of age to less than 2 years of age, dose does not exceed 0.2 mg/kg per day;
- b. If 2 years of age and older, weighing less than 20 kg, dose does not exceed 0.25 mg/kg per day;
- c. If 2 years of age and older, weighing 20 kg or more, dose does not exceed 5 mg per day.

**Reauthorization criteria: 12 months**

Spinal Muscular Atrophy (must meet all):

Yes  No Member does not require tracheostomy or invasive ventilation;

**AND**

Yes  No Member is responding positively to therapy as evidenced by one of the following (a, b, or c):

- a. For age < 2 years, must meet one of the following (i or ii):

- i. For CHOP-INTEND, must demonstrate score improvement or maintenance of previous score improvement of  $\geq 4$  points from baseline;
  - ii. For HINE motor milestone score, must demonstrate score improvement or maintenance of previous improvement in one or more categories AND improvement in more motor milestone categories than worsening;
- b. For age  $\geq 2$  years, must meet one of the following (i, ii, **or** iii):
- i. If first renewal since turning 2 years old, must provide submission of baseline HFMSE score, RHS score, RULM or ULM score, or 6MWT distance AND meet one of the following (1 **or** 2):
    - 1) For CHOP-INTEND, must demonstrate score improvement or maintenance of previous score improvement of  $\geq 4$  points from baseline;
    - 2) For HINE motor milestone score, must demonstrate score improvement or maintenance of previous improvement in one or more categories AND improvement in more motor milestone categories than worsening;
  - ii. If  $\leq 2$  years at therapy initiation and request is for subsequent renewal since turning 2, must meet one of the following
    - 1) For HFMSE, RHS, ULM or RULM, must demonstrate score improvement or maintenance of previous score improvement from baseline score submitted at first renewal since turning 2 years old;
    - 2) For 6MWT distance, must demonstrate improvement or maintenance of baseline distance;
  - iii. If  $> 2$  years at therapy initiation, must meet one of the following (1, 2, 3, **or** 4):

- 1) For HFMSE or RHS, must demonstrate score improvement or maintenance of previous score improvement of  $\geq 3$  points from baseline;
- 2) For ULM, must demonstrate score improvement or maintenance of previous improvements in  $\geq 2$  points from baseline;
- 3) For RULM, must demonstrate score improvement or maintenance of previous improvements in  $\geq 4$  points from baseline;
- 4) For 6MWT distance, must demonstrate improvement or maintenance of baseline distance

c. Member has not had a decline in motor function test score(s) from baseline **AND** medical justification demonstrates and supports that member is responding positively to therapy;

Yes  No Evrysdi is not prescribed concurrently with Spinraza and/or Zolgensma;

If request is for a dose increase, request meets one of the following (a, b, or c):

- a. If 2 months of age to less than 2 years of age, new dose does not exceed 0.2 mg/kg per day;
- b. If 2 years of age and older, weighing less than 20 kg, new dose does not exceed 0.25 mg/kg per day;
- c. If 2 years of age and older, weighing 20 kg or more, new dose does not exceed 5 mg per day

**See Package Insert for specific details on Contraindications/Warnings/Precautions**

### **Dosing**

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### **How Supplied:**