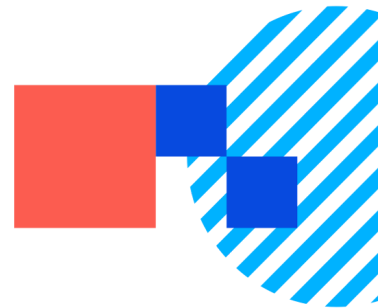




Risdiplam Prior Authorization

Drug(s) Applied:	Evrysdi (risdiplam)
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Criteria:

Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication and all of the following criteria are met:

I. Initial Therapy Criteria

A. Spinal Muscular Atrophy (SMA) as indicated by chart notes within past 120 days

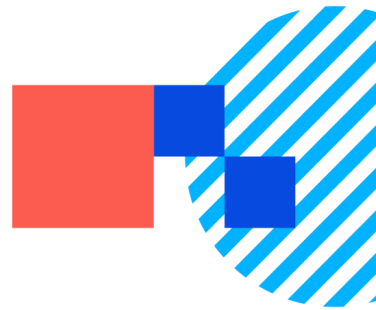
1. Diagnosis of SMA Type 1 **and**
2. Diagnosis is confirmed by genetic testing showing bi-allelic mutations in the SMN1 gene (homozygous deletion, homozygous mutation, or compound heterozygous mutation) **and**
3. SMN2 copy count of 2 or more **and**
4. At least ONE of the following functional assessments at baseline:
 - a) Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
 - b) Hammersmith Infant Neurological Examination (HINE)
 - c) Hammersmith Functional Motor Scale – Expanded (HFMSE)
 - d) Bayley Scales of Infant and Toddler Development (BSID)
 - e) Motor Function Measurement score (MFM32) **and**
5. Patient does not require invasive ventilation or tracheostomy **and**
6. Patient has not received gene therapy for SMA (e.g., Zolgensma, Itivisma) **and**
7. Patient will NOT be using the requested agent in combination with Spinraza (nusinersen) **and**
8. Prescriber is a specialist in the area of the patient's diagnosis (e.g., neurology, geneticist)

Approval Duration: 4months

II. Continued Therapy Criteria

A. Spinal Muscular Atrophy (SMA) as indicated by chart notes within past 120 days

1. Patient has SMA Type 1 **and**
2. Patient meets the initial therapy criteria above **and**
3. Documented clinical benefit since starting the requested agent as indicated by ONE of the following functional assessments showing improvements or



stabilization from baseline:

- a) Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
 - b) Hammersmith Infant Neurological Examination (HINE)
 - c) Hammersmith Functional Motor Scale – Expanded (HFMSE)
 - d) Bayley Scales of Infant and Toddler Development (BSID)
 - e) Motor Function Measurement score (MFM32) **and**
- 4. Patient does not require invasive ventilation or tracheostomy **and**
 - 5. Patient has not received gene therapy for SMA (e.g., Zolgensma, Itvisma) **and**
 - 6. Patient will NOT be using the requested agent in combination with Spinraza (nusinersen) **and**
 - 7. Prescriber is a specialist in the area of the patient's diagnosis (e.g., neurology, geneticist)

Approval Duration: 12 months

References:

1. Evrysdi prescribing information. Genentech, Inc. February 2025.
2. Zolgensma prescribing information. AveXis, Inc. February 2025.
3. Spinraza prescribing information. Biogen. April 2024.
4. Schroth, Michelle, et al. "Spinal Muscular Atrophy Update in Best Practices: Recommendations for Diagnosis Considerations." *Neurology: Clinical Practice*, vol. 14, no. 4, 2024, e200310. <https://doi.org/10.1212/CPJ.0000000000200310>

Policy Owned by: Curative PBM team