

Clinical Policy Title:	risdiplam
Policy Number:	RxA.663
Drug(s) Applied:	Evrysdi®
Original Policy Date:	12/07/2020
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Spinal Muscular Atrophy (must meet all):

1. Diagnosis of SMA.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Spinal Muscular Atrophy (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has met initial approval criteria.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. EVRYSDI® (risdiplam) for Oral Solution - [accessdata.fda.gov](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/213535s003s005lbl.pdf). (2022, May).
https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/213535s003s005lbl.pdf. Accessed October 5, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	10/15/2020	12/07/2020
Policy was reviewed: 1. Continued Therapy Approval II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 2. References were reviewed and updated.	10/20/2021	12/07/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.2: Updated to remove prior age criteria.	09/05/2022	10/19/2022

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<ol style="list-style-type: none"> 2. Initial Approval Criteria, I.A.2: Updated diagnostic criteria from Patient is 2 years old or older to Genetic testing confirms the presence of one of the following (a, b, or c): <ol style="list-style-type: none"> 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)]. 3. Initial Approval Criteria, I.A.8: Updated to include new documentation criteria If the member is currently on Spinraza®, documentation of prescriber attestation of Spinraza® discontinuation upon initiation of Evrysdi®. 4. Initial Approval Criteria, I.A.9: Updated to include new documentation criteria If the member has a history of treatment of Zolgensma®, provider must submit medical records (e.g., chart notes) documenting that there has been an inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months). 5. Continued Therapy Approval Criteria, II.A.2: Updated to include new criteria pertaining to indication Spinal Muscular Atrophy , Member does not require tracheostomy or invasive ventilation. 6. Continued Therapy Approval Criteria, II.A.4: Updated to include new combination therapy criteria Evrysdi is not prescribed concurrently with Spinraza and/or Zolgensma. 7. References were reviewed and updated. 		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: <ol style="list-style-type: none"> 1. Removed age restrictions. 2. Removed prescriber restrictions. 	10/16/2024	12/05/2024

<ul style="list-style-type: none"> 3. Removed requirement for being symptomatic. 4. Removed documentation requirement for prescriber attestation of Spinraza® discontinuation 5. Removed dose restrictions. 6. References were reviewed and updated. 		
<p>Policy reviewed.</p>	<p>12/11/2025</p>	<p>12/11/2025</p>