Clinical Policy Title:	risdiplam
Policy Number:	RxA.663
Drug(s) Applied:	Evrysdi®
Original Policy Date:	12/07/2020
Last Review Date:	12/05/2024
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. (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

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): 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 Crtieria, 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: 1. Removed age restrictions. 2. Removed prescriber restrictions.	10/16/2024	12/05/2024

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.		