Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Evrysdi (risdiplam)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial and continuation requests: 6 months

Medications	Quantity Limit
Evrysdi (risdiplam) 0.75 mg/mL oral solution	5 mg per day

APPROVAL CRITERIA

Initial requests for Evrysdi (risdiplam) may be approved if the following criteria are met:

I. Individual has a diagnosis of spinal muscular atrophy (SMA) by documentation of *either*:
   A. Spinal Muscular Atrophy (SMA) diagnostic test results confirming 0 copies of SMN1; **OR**
   B. Molecular genetic testing of 5q SMA for any of the following:
      1. Homozygous gene deletion; **OR**
      2. Homozygous conversion mutation; **OR**
      3. Compound heterozygote;

AND

II. Individual has documentation of SMA-associated signs and symptoms;

AND

III. Individuals is 2 months of age or older; **AND**

IV. Individual has documentation of genetic testing confirming 2 copies of SMN2 (NCT02913482); **AND**

V. Individual has documentation of symptom onset before 3 months of age (NCT02913482);

OR

VI. Individual is 2 years of age or older; **AND**

VII. Individual is non-ambulant as defined by being unable to walk unassisted for ≥ 10m (NCT02908685);

AND

VIII. Individual does not require use of invasive ventilation or tracheostomy as a result of advanced SMA disease.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Initial requests for Evrysdi (risdiplam) following treatment with Zolgensma (onasemnogene abeparvovec-xioi) may be approved if the following criteria are met:

I. When risdiplam therapy is determined to meet the above criteria; **AND**
II. Individual has experienced a decline in clinical status (for example, loss of motor milestone) since receipt of gene therapy.

Continuation requests for Evrysdi (risdiplam) may be approved if the following criteria are met:

I. When initial therapy was determined to meet the above criteria; **AND**
II. Individual has documentation of clinically significant improvement in spinal muscular atrophy-associated signs and symptoms (i.e., progression, stabilization, or decreased decline in motor function) compared to the predicted natural history trajectory of disease; **AND**
III. Individual does not require use of invasive ventilation or tracheostomy as a result of advanced SMA disease.

Requests for Evrysdi (risdiplam) may not be approved for the following:

I. Concomitant therapy with Spinraza (nusinersen).

Key References:

1. Bodamer OA, Nordli DR, Firth HV. Spinal muscular atrophy. Updated May 29, 2020. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: August 11, 2020.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. Clinicaltrials.gov [Internet]. Bethesda, MD: National Library of Medicine (US) 2000 Feb 29- . Identifier NCT02913482. A two Part seamless, open-label, multicenter study to investigate the safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy of RO7034067 in infants with type 1 spinal muscular atrophy: 2016 Sept 23 [cited 2020 Jan 29]. Available from: https://clinicaltrials.gov/ct2/show/study/NCT02913482. Accessed on January 29, 2020.
6. Clinicaltrials.gov [Internet]. Bethesda, MD: National Library of Medicine (US) 2000 Feb 29- . Identifier NCT02908685. A two part seamless, multi-center randomized, placebo-controlled, double-blind study to investigate the safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy of RO7034067 in Type 2 and 3 spinal muscular atrophy patients: 2016

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Sept 21 [cited 2020 Jan 29]. Available from: https://clinicaltrials.gov/ct2/show/study/NCT02908685. Accessed on January 29, 2020.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.