CareSource

PHARMACY POLICY STATEMENT **Ohio Medicaid**	
DRUG NAME	Evrysdi (risdiplam)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— see "Dosage Allowed"
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Evrysdi (risdiplam) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

SPINAL MUSCULAR ATROPHY (SMA)

For **initial** authorization:

1. Member is 2 months of age or older; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a confirmed diagnosis of 5q-autosomal recessive spinal muscular atrophy (SMA) Type 1, 2, or 3 as evidenced by genetic testing results showing **both** of the following;
   a) Mutation or deletion in SMN1 genes with **one** of the following:
      i) Homozygous deletion of SMN1 genes (zero copies of SMN1 genes);
      ii) Homozygous mutation in SMN1 genes;
      iii) Compound heterozygous mutation in SMN1 genes (deletion of one SMN1 gene and mutation of another SMN1 gene; AND
   b) 2 to 4 copies of SMN2; AND
4. Member has documentation of a baseline evaluation of current clinical status or motor function (e.g., Hammersmith Functional Motor Scale Expanded (HFMSE), Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND), Hammersmith Infant Neurological Exam (HINE), Revised Upper Limb Module (RULM), Motor Function Measure 32 (MFM32), 6 minute walk test, etc.); AND
5. Member does not have prior treatment with Zolgensma; AND
6. Medication will not be used together with Spinraza. Any current use must be discontinued prior to starting treatment with Evrysdi; AND
7. Member does not require the use of invasive ventilation or tracheostomy as a result of advanced SMA disease.
8. **Dosage allowed:** 2 months to < 2 years of age: 0.2 mg/kg once daily; 2 years of age and older weighing < 20 kg: 0.25 mg/kg once daily; 2 years of age or older weighing 20 kg or more: 5 mg once daily.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Documentation has been provided showing that member has had improvement or stabilization in clinical status and motor function since baseline; AND
2. Medication will not be used together with Spinraza or Zolgensma.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Evrysdi (risdiplam) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
09/16/2020	New policy for Evrysdi created.

References:

1. Evrysdi [package insert]. South San Francisco, CA: Genetech, Inc.; August 2020.
2. Mercuri E, Finkel RS, Muntoni F, et al. Diagnosis and management of spinal muscular atrophy: Part 1: Recommendations for diagnosis, rehabilitation, orthopedic and nutritional care. *Neuromuscul Disord*. 2018;28(2):103-115. doi:10.1016/j.nmd.2017.11.005.
3. Dangouloff T, Servais L. Clinical Evidence Supporting Early Treatment Of Patients With Spinal Muscular Atrophy: Current Perspectives. *Ther Clin Risk Manag*. 2019;15:1153-1161. Published 2019 Oct 2. doi:10.2147/TCRM.S172291.
4. Wang CH, Finkel RS, Bertini ES, et al. Consensus statement for standard of care in spinal muscular atrophy. *J Child Neurol*. 2007;22(8):1027-1049. doi:10.1177/0883073807305788.
5. ClinicalTrials.gov. A study to investigate the safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy of risdiplam (RO7034067) in Type 2 and Type 3 Spinal Muscular Atrophy (SMA) participants (SUNFISH). Identifier: NCT02908685. Available at: https://clinicaltrials.gov/ct2/show/NCT02908685.
6. ClinicalTrials.gov. Investigate safety, tolerability, PK, PD, and efficacy of risdiplam (RO7034067) in infants with Type 1 Spinal Muscular Atrophy (FIREFISH). Identifier: NCT02913482. Available at: https://clinicaltrials.gov/ct2/show/NCT02913482.
7. CureSMA. The genetics of spinal muscular atrophy. www.cureSMA.org. Elk Grove Village, IL. Accessed on Sep 16, 2020.
8. Finkel RS, Mercuri E, Darras BT, et al. Nusinersen versus Sham Control in Infantile-Onset Spinal Muscular Atrophy. *N Engl J Med*. 2017;377(18):1723-1732. doi:10.1056/NEJMoa1702752.

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