Pharmacy Drug Policy & Procedure

Policy Name:	Evrysdi (risdiplam)	Policy #:	2791P

Purpose of the Policy

The purpose of this policy is to define the criteria for coverage of Evrysdi (risdiplam).

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Evrysdi (risdiplam) under the specialty pharmacy benefit when the following criteria have been met.

Criteria

1. Coverage Criteria

1.1 Diagnosis of Spinal Muscular Atrophy (SMA) types I, II, or III

1.2 Documentation of 5q SMA double gene mutation, double gene deletion, or compound heterozygote

1.3 Prescribed by a Geneticist (gene specialist) or provider specializing in the treatment of SMA

1.4 Documented baseline motor milestone scores according to one of the following age-appropriate assessments:

- Hammersmith Infant Neurologic Exam (HINE)
- Modified Hammersmith Functional Motor-Scale
- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
- Bayley Scales of Infant and Toddler Development
- Motor Function Measure 32 (MFM32)

1.5 Chart notes from a recent specialist visit detailing member's present disease progression and respiratory function

1.6 Review of chart notes documenting diagnosis and confirming that patient has met all of the requirements for treatment with Evrysdi by both a pharmacist and medical director

2. Exclusion Criteria

2.1 Evrysdi will not be covered after treatment with Zolgensma because its use following Zolgensma infusion is currently in clinical trials without confirmed efficacy data and is currently considered experimental/investigational

- Note: Patients in the clinical trials that received Zolgensma before the age of 2 years were followed up to 5 years post-treatment and did not require additional medications
- Requests for Evrysdi in members that have previously been treated with Zolgensma will be reviewed by a Medical Director for medical necessity

2.2 Evrysdi will not be covered in combination with Spinraza because the concomitant use of these two drugs has not been studied and is considered experimental/investigational

- Requests for Evrysdi in members that have previously been treated with Spinraza will be reviewed by a Medical Director for medical necessity

2.3 Replacement of lost, wasted, or discarded doses will not be covered.

- Health Alliance's standard refill threshold will apply

3. Managed Dose Limit

3.1 #200mL per 30 days

- MDL is based upon a maximum daily dose of 5mg

4. Approval Period

4.1 Initial Approval: 12 months

4.2 Subsequent Approvals: 12 months with documented refill compliance and improvement of motor milestone scores according to Hammersmith Infant Neurologic Exam (HINE), Modified Hammersmith Functional Motor-Scale, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), Bayley Scales of Infant and Toddler Development, Motor Function Measure 32 (MFM32)

CPT Codes	

HCPCS Codes	

References

1. Evrysdi (risdiplam) [prescribing information]. South San Francisco, CA: Genentech Inc; March 2023.
2. Finkel RS, Mercuri E, Meyer OH, et al; SMA Care group. Diagnosis and management of spinal muscular atrophy: Part 2: Pulmonary and acute care; medications, supplements and immunizations; other organ systems; and ethics. Neuromuscul Disord. 2018 Mar;28(3):197-207.
3. Baranello G, Darras BT, Day JW, et al. Risdiplam in Type 1 Spinal Muscular Atrophy. N Engl J Med 2021; 384:915.
4. Mercuri E, Deconinck N, Mazzone ES, et al. Safety and efficacy of once-daily risdiplam in type 2 and non-ambulant type 3 spinal muscular atrophy (SUNFISH part 2): a phase 3, double-blind, randomised, placebo controlled trial. Lancet Neurol 2022; 21:42.

Created Date: 10/21/20
Effective Date: 10/21/20
Posted to Website: 01/01/2022
Revision Date: 10/04/2023

DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.