Coverage Policy Manual

Policy #: 2025027
Category: Pharmacy
Initiated: November 2025
Last Review: September 2026
Last Revision: September 2026

Risdiplam (e.g., Evrysdi)

Description:

Spinal muscular atrophy (SMA) is an inherited disorder caused by homozygous deletions or variants in the *SMN1* gene in chromosome 5. This gene is responsible for producing the "survival of motor neuron" protein (SMN1). Because of absent or low levels of survival motor neuron 1 protein, the motor neurons in spinal cord degenerate, resulting in atrophy of the voluntary muscles of the limbs and trunk. During early development, these muscles are necessary for crawling, walking, sitting up, and head control. The more severe types of SMA can also affect muscles involved in feeding, swallowing, and breathing. Treatments include:

1. **Nusinersen (e.g., Spinraza) (see policy number 2019011)** is a synthetic antisense oligonucleotide designed to bind to a specific sequence in exon 7 of the SMN2 transcript causing the inclusion of exon 7 in the SMN2 transcript, leading to the production of full length functional survival motor neuron 2 protein, which is very similar to SMN1.
2. **Onasemnogene abeparvovec-xioi (e.g., Zolgensma) (see policy number 2025026)** is an adeno-associated virus vector-based gene therapy and is intended as a one-time gene replacement therapy designed to deliver a functional copy of the SMN1 gene to motor neuron cells of individuals with spinal muscular atrophy. Because motor neurons are nondividing cells, it is postulated that once the SMN1 gene is incorporated in the cells, it would be retained over time and potentially allow for long-term, sustained survival motor neuron protein expression.
3. **Risdiplam (e.g., Evrysdi)** is a once-daily self-administered oral therapy. It is a selective SMN2 splicing modifier designed to bind with specificity to SMN2 pre-mRNA to modulate SMN2 pre-mRNA splicing towards the production of full-length SMN2 mRNA.

The exact role of the SMN protein in motoneurons has not been completely elucidated and levels of the SMN protein required for optimal functioning are unknown (Wang, 2007). *SMN2* is a nearly identical modifying gene capable of producing nearly identical compensatory SMN2 protein. However, 70% to 90% of the transcripts produced from the *SMN2* gene produce a truncated protein that is defective and unstable due to lack of exon 7 (Lorson, 1999). Further, humans exhibit variability (range, 0-6) in the number of copies of the *SMN2* gene and copy number is inversely proportional to severity of disease (Lefebvre, 1997). These factors in tandem lead to wide variability in disease severity.

SMA is classified into 4 main categories (with additional subcategories) based on the age at the onset of symptoms (Muscular Dystrophy Association, 2017; National Organization for Rare Disorders, 2012). Generally, early onset of disease directly correlates to severity of symptom and rate of disease progression. There is no exact marker to classify these categories, and they are not well-distinguished by ICD-10-CM code.

- Type 0: The most severe form of SMA, symptoms can often be seen in the later stages of pregnancy. Fetal movements are less than expected and, after birth, the infant will have little ability to move and may not be able to breathe and swallow independently. Death occurs before the age of 6 months. SMN2 copy number 1.
- Type I (also called infantile SMA or Werdnig-Hoffman disease and subcategorized as IA, IB and IC): Onset within 6 months of birth and symptoms progress rapidly, and most infants die before 1 year of age from respiratory failure. About 60% of individuals with SMA constitute of this phenotype. SMN2 copy number 2. (Zerrres, 1995; Finkel, 2017).
- Type II (also called intermediate SMA or Dubowitz disease): Onset within 6 to 18 months with a less severe progression. Typically, a child can sit independently if positioned, but is unable to walk. More than 70% of individuals live beyond 25 years of age with adequate supportive care. SMN2 copy number 3 or 4
- Type III (also called Kugelberg-Welander disease and subcategorized as IIIA and IIIB): Onset after 18 months of age. Lifespan is not affected, with wide-ranging reduction in muscle strength with a chronic course. The outcome depends primarily on the severity of muscle weakness at presentation rather than age of onset, but earlier onset tends to correlate with greater weakness. SMN2 copy number 3 or 4.
- Type IV (also called adult-onset SMA): Usually presents in the third decade of life and is otherwise similar to SMA type III. SMN2 copy number 4-8.

The prevalence of SMA is estimated to be between 9.1 and 10 per 100,000 live births (Prior, 2010; Sugarman, 2012). In 95% cases, both copies of the SMN1 exon 7 are absent. The remaining 5% cases are compound heterozygotes for *SMN1* exon 7 deletion and small intragenic variants. The molecular diagnosis of SMA consists of the detection of the absence of exons 7 of the *SMN1* gene in the majority of cases (Prior, 2010).

Regulatory Status

On August 7, 2020, the FDA approved risdiplam (e.g., Evrysdi) to treat individuals 2 months and alder with SMA. This is the first oral drug to treat this disease.

Coding

See CPT/HCPCS Code section below.

Policy/ Coverage:

For coverage prior to November 15, 2025, please refer policy number 2019011, Treatment for Spinal Muscular Atrophy.

The FDA has deemed this drug to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, the use of Risdiplam is not covered under the medical benefit. Please check the member's pharmacy benefit for coverage. This policy applies to members whose plan utilizes AR BCBS pharmacy and has Risdiplam as a formulary option.

INITIAL AND CONTINUATION APPROVAL will be for duration of treatment course or 12 months (whichever comes first). Approval timeframes may differ for members/participants of Self-Insured plans.

Effective October 01, 2026

Meets Primary Coverage Criteria Or Is Covered For Contracts Without Primary Coverage Criteria

INITIAL APPROVAL:

Risdiplam (e.g., Evrysdi) meets member benefit certificate **Primary Coverage Criteria** that there be scientific evidence of effectiveness in improving health outcomes or for members with contracts **without Primary Coverage Criteria,** is considered **Medically Necessary** and is covered, when **ALL** the following criteria are met:

1. Diagnosis of spinal muscular atrophy confirmed by genetic testing demonstrating bi-allelic mutations in the survival motor neuron 1 (*SMN1*) gene as stated below (Gene Reviews, SMA 2020):
    a. Deletion of both copies of the *SMN1* gene; **OR**
    b. Identification of pathogenic variant(s) in both copies of the *SMN1* gene; **AND**
2. Individual meets one of the following (Mercuri 2020):
    a. Individual has less than four copies of SMN2 – laboratory documentation must be provided; **OR**
    b. Individual has four copies of SMN2 and developed SMA-associated symptoms prior to 21 years of age – laboratory documentation and documentation from the medical record must be provided; **AND**
3. Individual age is less than 25 years of age (Mercuri, 2020); **AND**
4. Individual is not on permanent ventilator dependence; **AND**
5. Individual is not concurrently enrolled in a clinical trial for any experimental therapy for spinal muscular atrophy; **AND**
6. Prescribed by a neurologist with expertise in treating spinal muscular atrophy.

Note: The concurrent use of risdiplam with onasemnogene abeparvovec-xioi and/or nusinersen is not covered (see statement of non-coverage below).

AUTHORIZATION RENEWAL:

1. Condition stable or improved with treatment with documentation of most recent results (less than 1 month prior to request) demonstrating a positive clinical response from pretreatment baseline status to risdiplam therapy as demonstrated by at least one of the following:
    a. HINE-2 milestones; **OR**
    b. HFMSE; **OR**
    c. ULM; **OR**
    d. CHOP INTEND; **OR**
    e. PT/OT evaluation notes demonstrating improvement from pretreatment results; **AND**
2. Individual is not dependent on either of the following:
    a. Invasive ventilation or tracheostomy; **OR**
    b. Use of non-invasive ventilation beyond use of naps and nighttime sleep; **AND**
3. Manageable or no side effects; **AND**
4. Nusinersen is prescribed by or in consultation with, a neurologist with expertise in the treatment of SMA.

Does Not Meet Primary Coverage Criteria Or Is Not Covered For Contracts Without Primary Coverage Criteria

Risdiplam (e.g., Evrysdi), for any indication or circumstance not described above, does not meet member benefit certificate **Primary Coverage Criteria** that there be scientific evidence of effectiveness in improving health outcomes and is not covered including but not limited to:

1. Concurrent use of risdiplam with onasemnogene abeparvovec-xioi and/or nusinersen.

For members with contracts without **Primary Coverage Criteria**, Risdiplam (e.g., Evrysdi) for any indication or circumstance not described above, is considered not **Medically Necessary** and is not covered or is **Investigational**. **Not Medically Necessary** or **Investigational** services are specific contract exclusions in most member benefit certificates of coverage including but not limited to:

1. Concurrent use of risdiplam with onasemnogene abeparvovec-xioi and/or nusinersen.

Please refer to separate policy on Site of Care or Site of Service Review (policy #2018030) for pharmacologic/biologic medications.

Effective November 15, 2025 to September 30, 2026

Meets Primary Coverage Criteria Or Is Covered For Contracts Without Primary Coverage Criteria

INITIAL APPROVAL:

Risdiplam (e.g., Evrysdi) meets member benefit certificate primary coverage criteria that there be scientific evidence for effectiveness in improving health outcomes for the treatment of individuals type I, type II and type III SMA if **ALL** the following conditions are met:

1. Diagnosis of spinal muscular atrophy confirmed by genetic testing demonstrating bi-allelic mutations in the survival motor neuron 1 (*SMN1*) gene as stated below (Gene Reviews, SMA 2020):
    a. Deletion of both copies of the *SMN1* gene; **OR**
    b. Identification of pathogenic variant(s) in both copies of the *SMN1* gene; **AND**
2. Individual meets one of the following (Mercuri 2020):
    a. Individual has less than four copies of SMN2 – laboratory documentation must be provided; **OR**
    b. Individual has four copies of SMN2 and developed SMA-associated symptoms prior to 21 years of age – laboratory documentation and documentation from the medical record must be provided; **AND**
3. Individual age is less than 25 years of age (Mercuri, 2020); **AND**
4. Individual is not on permanent ventilator dependence; **AND**
5. Individual is not concurrently enrolled in a clinical trial for any experimental therapy for spinal muscular atrophy; **AND**
6. Prescribed by a neurologist with expertise in treating spinal muscular atrophy.

Note: The concurrent use of risdiplam with onasemnogene abeparvovec-xioi and/or nusinersen is not covered (see statement of non-coverage below).

CONTINUATION APPROVAL:

Incremental reauthorization for risdiplam for 1 year may be considered **medically necessary** if the following conditions 1 and 2 are met:

1. Individual was previously approved for risdiplam based on criteria cited above; **AND**
2. Individual is not dependent on either of the following:
    a. Invasive ventilation or tracheostomy; **OR**
    b. Use of non-invasive ventilation beyond use of naps and nighttime sleep; **AND**
3. Submission of medical records (e.g., chart notes, laboratory values) with the most recent results (less than 1 month prior to request) documenting a positive clinical response from pretreatment baseline status to risdiplam therapy as demonstrated by at least one of the following exams:
    a. HINE-2 milestones; **OR**
    b. HFMSE; **OR**
    c. ULM; **OR**
    d. CHOP INTEND; **OR**
    e. PT/OT evaluation notes demonstrating improvement from pretreatment results; **AND**
4. Nusinersen is prescribed by or in consultation with, a neurologist with expertise in the treatment of SMA.

Does Not Meet Primary Coverage Criteria Or Is Not Covered For Contracts Without Primary Coverage Criteria

Risdiplam (e.g., Evrysdi), for any indication or circumstance not described above, does not meet member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes including but not limited to:

1. Concurrent use of risdiplam with onasemnogene abeparvovec-xioi and/or nusinersen.

For those members without primary coverage criteria, Risdiplam (e.g., Evrysdi) for any indication or circumstance not described above, is considered **investigational** including but not limited to:

1. Concurrent use of risdiplam with onasemnogene abeparvovec-xioi and/or nusinersen.

Investigational services are specific contract exclusions in most member benefit certificates of coverage.

Please refer to separate policy on Site of Care or Site of Service Review (policy #2018030) for pharmacologic/biologic medications.

Rationale:

Spinal Muscular Atrophy Type I
For individuals who have symptomatic SMA type I (infantile onset) who receive risdiplam, the evidence includes 1 single arm prospective phase 2/3 FIREFISH study. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Results of a part 1 study (dose-finding and exploratory) in which 4 patients received low dose and 17 patients received high dose risdiplam are available. The results of the part 1 study (dose-finding and exploratory) showed 41 % (7 of 17 infants) were able to sit without support for at least 5 seconds as assessed by BSID-I11 after 12 months of treatment. After a minimum follow-up of 12 and 23 months of treatment with risdiplam, 90% (19/21) and 81% (17/21) of patients were alive without permanent ventilation. The observed treatment effect on motor functions and event-free survival is beyond what typical is based on the known natural history of patients with SMA type I with 2 copies of SMN2. However, there is limited data to assess the long-term durability of treatment effect as well as safety related to adverse events that are rare or have delayed onset.

Spinal Muscular Atrophy Type II and III
The evidence for pediatric or adult patients (2-25 years old) with type II or III SMA patients includes the ongoing double blind, 2-part, placebo-controlled SUNFISH study.

Part 1 was dose-finding and exploratory in 51 patients for 12 weeks. Part 2 was the randomized, double-blind, placebo controlled in which patients received risdiplam or placebo for 12 months. After 12 months, placebo recipients were switched to risdiplam for next 12 months while those receiving risdiplam continued to receive until 24 months. This trial included patient population who previously were excluded from clinical trials, such as ages up to 25, severe scoliosis, and low baseline function. At baseline, 67% of patients had scoliosis (32% of them with severe scoliosis). Results of Part 2 are discussed next. The least square mean change in MFM-32 from baseline was greater in patients receiving risdiplam compared with placebo with a difference of 1.55 (95% CI: 0.30 to 2.81). Responder analysis (using a threshold of increase in 3 or more points in MFM-32 as being clinically meaningful) showed that 38% of those receiving risdiplam met the criteria of achieving a clinically meaningful improvement in motor function compared to 24% in the placebo arm. Clinical benefit was also observed in the upper limb function as measured by revised upper limb module (RULM). Risdiplam treated patients had a mean 1.6-point improvement from baseline at month 12 compared to no mean score change in the placebo group (p=0.047). In general, increases on motor function tests would not be expected in the natural history of Type 2 and 3 SMA, and the differences observed between patients treated with risdiplam and those on placebo are considered clinically meaningful. (Center for Drug Evaluation and Research, 2020)

For MFM-32, and RULM subgroup analysis based on SMA subtype showed treatment differences in favor of risdiplam versus placebo in both SMS type 2 and 3. Subgroup analysis based on SMN2 copy number showed treatment differences in favor of risdiplam versus placebo based upon point estimates in individuals with 3 and 4 copies. However, the confidence intervals were wide and specifically for individuals with SMN2 copy number 4, the confidence interval was inclusive of negative treatment effect. There were only 4 participants with 2 SMN2 2 copy numbers and there was a negative treatment effect.

Risdiplam is an oral, survival of motor neuron 2 (SMN2) pre-mRNA splicing modifier approved for the treatment of spinal muscular atrophy (SMA). SUNFISH (NCT02908685) Part 2, a Phase 3, randomized, double-blind, placebo-controlled study, investigated the efficacy and safety of risdiplam in type 2 and non-ambulant type 3 SMA. The primary endpoint was met: a significantly greater change from baseline in 32-item Motor Function Measure (MFM32) total score was observed with risdiplam compared with placebo at month 12. After 12 months, all participants received risdiplam while preserving initial treatment blinding. We report 24-month efficacy and safety results in this population. Month 24 exploratory endpoints included change from baseline in MFM32 and safety. MFM-derived results were compared with an external comparator. At month 24 of risdiplam treatment, 32% of patients demonstrated improvement (a change of ≥ 3) from baseline in MFM32 total score; 58% showed stabilization (a change of greater than or equal to 0). Compared with an external comparator, a treatment difference of 3.12 (95% confidence interval [CI] 1.67-4.57) in favor of risdiplam was observed in MFM-derived scores. Overall, gains in motor function at month 12 were maintained or improved upon at month 24. In patients initially receiving placebo, MFM32 remained stable compared with baseline (0.31 [95% CI - 0.65 to 1.28]) after 12 months of risdiplam; 16% of patients improved their score and 59% exhibited stabilization. The safety profile after 24 months was consistent with that observed after 12 months. Risdiplam over 24 months resulted in further improvement or stabilization in motor function, confirming the benefit of longer-term treatment. (Oskoui M, Day JW, Deconinck N, 2023)

Study 1 was an open-label, 2-part study to investigate the efficacy, safety, pharmacokinetics, and pharmacodynamics of EVRYSDI for oral solution in patients with Type 1 SMA (symptom onset between 28 days and 3 months of age). All patients had genetic confirmation of homozygous deletion or compound heterozygosity predictive of loss of function of the SMN1 gene, and two SMN2 gene copies.

Part 1 of Study 1 was designed as a dose-finding study. Part 2 of Study 1 assessed the safety and efficacy of EVRYSDI at 0.20 mg/kg, the recommended dose determined in Part 1. Patients from Part 1 did not take part in Part 2.

A total of 62 patients with symptomatic Type 1 SMA were enrolled in FIREFISH Part 1 (n = 21) and Part 2 (n = 41), of which 58 patients received the recommended dosage. The median age of onset of clinical signs and symptoms was 1.5 months (range: 0.9 to 3.0 months). The median age at enrollment was 5.6 months (range: 2.2 to 6.9 months), and the median time between onset of symptoms and the first dose was 3.7 months (range 1.0 to 6.0 months). Of these patients, 60% were female, 57% were Caucasian, and 29% were Asian. The demographics and baseline disease characteristics were comparable between Part 1 and Part 2 of the study.

Effectiveness was established based on the ability to sit without support for at least 5 seconds (as measured by Item 22 of the Bayley Scales of Infant and Toddler Development – Third Edition (BSID-III) gross motor scale) and on the basis of survival without permanent ventilation.
Permanent ventilation was defined as requiring a tracheostomy or more than 21 consecutive days of either non-invasive ventilation (≥ 16 hours per day) or intubation, in the absence of an acute reversible event.

The primary endpoint was the proportion of patients with the ability to sit without support for at least 5 seconds (BSID-III gross motor scale, Item 22) after 12 months of treatment in Part 2; 29% of patients (n = 12/41) achieved this milestone.

At Month 24, 40% (23/58) of patients who received the recommended dose achieved sitting without support for 30 seconds (BSID-III, Item 26). In addition at Month 24, patients continued to achieve additional motor milestones; 28% (16/58) of patients achieved a standing measure
(16% [9/58] supporting weight and 12% [7/58] standing with support), as measured by Section 2 of the Hammersmith Infant Neurological Examination (HINE-2) which assesses motor milestones.

The proportion of patients alive without permanent ventilation (event-free survival) was 84% for all patients at Month 24 (Table 3). Out of 62 patients, 6 infants died (4 within the first 3 months following study enrollment) and one additional patient withdrew from treatment and died 3.5
months later. Four patients required permanent ventilation by Month 24. These results indicate a clinically meaningful deviation from the natural history of untreated infantile-onset SMA. As described in the natural history of untreated infantile-onset SMA, patients would not be expected to attain the ability to sit independently, and no more than 25% of these patients would be expected to survive without permanent ventilation beyond 14 months of age.

2026 Update

Annual policy review completed with a literature search using the MEDLINE database through September 2026. No changes to coverage statements.

CPT/HCPCS:

C9399	Unclassified drugs or biologicals
J3490	Unclassified drugs
J3590	Unclassified biologics

Revisions:

September 2025	New policy effective 11/15/2025, separated from policy number 2019011.
September 2026	Rationale updated. Policy reformatted with no change in coverage statement

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Group specific policy will supersede this policy when applicable. This policy does not apply to the Wal-Mart Associates Group Health Plan participants.

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