Louisiana Medicaid
Risdiplam (Evrysdi®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for risdiplam (Evrysdi®).

Additional Point-of-Sale edits may apply.

*This agent may have a **Black Box Warning** and may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Approval Criteria

- The recipient has a diagnosis of spinal muscular atrophy (SMA):
  - Type I, also known as infantile-onset or Werdnig-Hoffmann disease (ICD-10-CM G12.0), symptoms are present at birth or by 6 months of age, unable to sit without assistance; **OR**
  - Type II (ICD-10-CM G12.1), symptoms develop between 6 months and 12 months of age, able to sit unassisted but unable to stand or walk independently; **OR**
  - Type III, also known as Kugelberg-Welander disease (ICD-10-CM G12.1), usually diagnosed between early childhood and early adolescence, able to stand and walk independently but may lose this ability later in life; **AND**
- The prescriber **states on the** request that the diagnosis of SMA has been confirmed with genetic testing; **AND**
- ~~The recipient is 2 months of age or older on the date of the request; **AND**~~
- The medication is prescribed by, or **the request states** that it is in consultation with, a physician who specializes in the treatment of spinal muscular atrophy; **AND**
- The recipient has not previously received treatment with Zolgensma® (onasemnogene abeparvovec-xioi); **AND**
- The recipient is not using the requested medication concurrently with Spinraza® (nusinersen); **AND**
- **ONE** of the following motor milestone tests have been performed and the results are noted on the request form:
  - For recipients with SMA Type 1, the Bayley Scales of Infant and Toddler Development – Third Edition (BSID-III) gross motor scale [or its successor publications]; **OR**
  - For recipients with SMA Type 2 or Type 3, the Motor Function Measure 32 (MFM32); **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**

- The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling; **AND**
- The recipient does not have a coexisting terminal condition or a condition with which the risk of risdiplam treatment outweighs the potential benefits.

Reauthorization Criteria

- Recipient continues to meet initial approval criteria; **AND**
- For recipients with Type I SMA, the prescriber **states on the request** that there has been a positive clinical benefit from risdiplam therapy as evidenced by **stating on the request** that there has been:
  - improvement or maintenance of 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 [or its successor publications]); **AND**
  - survival without permanent ventilation; permanent ventilation is 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; **OR**
- For recipients with Type 2 or Type 3 SMA, the prescriber **states on the request** that there has been a positive clinical benefit from risdiplam therapy as evidenced by **stating on the request** that there has been:
  - a 3-point or greater change from baseline to Month 12 in the Motor Function Measure 32 (MFM32) score; **OR**
  - a change from baseline in total score of the Revised Upper Limb Module (RULM) at Month 12.

Duration of initial and reauthorization approval: 12 months

References

Evrysdi (risdiplam) [package insert]. South San Francisco, CA: Genentech, Inc. A Member of the Roche Group; May~~April~~ 2021. https://www.gene.com/download/pdf/evrysdi_prescribing.pdf

U.S. National Library of Medicine. Genetics Home Reference. (2018, September 25). Spinal Muscular Atrophy. ~~Retrieved from~~ https://ghr.nlm.nih.gov/condition/spinal-muscular-atrophy

Revision / Date	Implementation Date
Policy Created / August 2020	January 2021
Removed POS wording, formatting changes, updated references / May 2021	January 2022
Removed age requirement, updated references / June 2022	October 2022