STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Services
Prior Authorization Criteria
Evrysdi® (Risdiplam)
Effective 11/1/2022

Prior Authorization Request Form

Evrysdi *is a survival of motor neuron 2 (SMN2) splicing modifier indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.*

CRITERIA FOR APROVAL:

1. Evrysdi must be prescribed by, or in consultation with, a neurologist or a neuromuscular specialist in the treatment of spinal muscular atrophy; **AND**

2. Documentation must be submitted showing the patient has a diagnosis of Spinal Muscular Atrophy (SMA) confirmed by genetic testing; **AND**

3. The patient must be within the age range as recommended by the FDA label and indication; **AND**

4. The patient does not have hepatic impairment; **AND**

5. The patient must not have advanced SMA and does not require the use of permanent ventilation or tracheostomy; **AND**

6. Females of childbearing potential should have a negative pregnancy test collected within 30 days prior to the initiation of therapy. All patients must commit to use effective contraception during treatment and for at least 1 month after the last dose and the provider should monitor/counsel patients regarding pregnancy risk; **AND**

7. Patient is not concurrently being treated with Spinraza; **AND**

8. Patient has not received prior treatment with Zolgensma; **AND**

9. Obtain and provide documentation of a baseline assessment motor milestone score from at least **ONE** of the following assessments:

1- Hammersmith Functional Motor Scale Expanded (HFMSE)
2- Hammersmith Infant Neurologic Exam (HINE)
3- Upper limb module (ULM) score or Revised upper limb module (RULM) score
4- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
5- Six-minute walk test
6- Bayley Scales of Infant and Toddler development Third Ed. (BSID-III)
7- Motor Function Measure-32 Items (MFM-32)

CONTINUATION OF THERAPY:

1. Patient must continue to meet all initial prior authorization criteria; **AND**

2. Documented evidence must be submitted showing clinically significant improvement in SMA associated symptoms, such as lack of progression, stabilization, or decreased decline in motor function, as compared to the natural history trajectory of the disease by submission of medical records with the most recent results (**≤ 6 month prior to request**) documenting a positive clinical response from pretreatment baseline status to Evrysdi therapy as demonstrated by at least **ONE** of the following assessments:

1- Hammersmith Functional Motor Scale Expanded (HFMSE)
2- Hammersmith Infant Neurologic Exam (HINE)
3- Upper limb module (ULM) score or Revised upper limb module (RULM) score
4- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
5- Six-minute walk test
6- Bayley Scales of Infant and Toddler development Third Ed. (BSID-III)
7- Motor Function Measure-32 Items (MFM-32)

Approval Duration: Initial approval will be granted for 6 months and continuation will be granted for 12 months.

References:

1.) Evrysdi Package Insert
2.) Lexi-Comp Clinical Application 2/2021, 11/2022
3.) UpToDate Clinical monograph: Spinal muscular atrophy reviewed 2/2021
4.) 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.