Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	September 21, 2020 December 15, 2020, December 17, 2021, January 12, 2022, October 14, 2022

EVRYSDI® (risdiplam)

LENGTH OF AUTHORIZATION: 6 months

REVIEW CRITERIA (medical records must be submitted):

- Confirmed diagnosis of spinal muscular atrophy (SMA) confirmed by genetic testing.
    - Documentation of genetic testing confirming either two or three copies of SMN2 gene;
      OR
      Documentation of genetic testing confirming four copies of SMN2 gene with symptomatology of SMA
    - Genetic testing confirms the presence of one of the following:
      a. Homozygous deletion or mutation of SMN1 gene OR
      b. Compound heterozygous mutation of SMN1 gene
- Medication is prescribed or in consultation with a pediatric neuromuscular specialist or a neurologist specializing in SMA.
- Patient must not have advanced SMA and is not dependent on either of the following:
    - Invasive ventilation (for not more than 16 hours per day) or tracheostomy OR
    - Non-invasive ventilation for at least 12 hours per day
- Females of childbearing potential should have a negative pregnancy test collected within 30 days prior to the initiation of therapy.
    - Female and male patients must commit to use effective contraception during treatment and for at least 1 month after the last dose.
    - The provider should monitor/counsel patients regarding pregnancy risk.
- Obtain baseline assessment motor milestone score from ONE of the following assessments:
    - Hammersmith Functional Motor Scale Expanded (HFMSE)
    - Hammersmith Infant Neurologic Exam (HINE)
    - Upper limb module (ULM) score
    - Revised upper limb module (RULM) score
    - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
    - Six-minute walk test
- Patient is not concurrently treated with Spinraza.

CONTINUATION OF THERAPY:

- Patient met initial review criteria.
- Patient must not have advanced SMA and is not dependent on either of the following:
    - Invasive ventilation (for not more than 16 hours per day) or tracheostomy OR
    - Non-invasive ventilation for at least 12 hours per day

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- Females of childbearing potential should have a negative pregnancy test collected within 30 days.
    - Female and male patients must commit to use effective contraception during treatment and for at least 1 month after the last dose
    - The provider should monitor/counsel patients regarding pregnancy risk.
- Documentation of a positive response to therapy and that the patient is responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pretreatment baseline status (progression, stabilization, or decreased decline in motor function) from ONE of the following age appropriate assessments:
    - Hammersmith Functional Motor Scale Expanded (HFMSE)
    - Hammersmith Infant Neurologic Exam (HINE)
    - Upper limb module (ULM) score
    - Revised upper limb module (RULM) score
    - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
    - Six-minute walk test
- Patient is not concurrently treated with Spinraza.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as a 60mg powder for constitution to provide 0.75 mg/mL solution.