Reference number(s)
4074-A

Specialty Guideline Management
Evrysdi

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Evrysdi	risdiplam

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Evrysdi is indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initiation of Therapy

- Deletion or mutation at the SMN1 allele confirmed by genetic testing

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- Medical records (e.g., chart notes, laboratory values) of the baseline assessment for at least one of the following assessment tools (based on patient age and motor ability) to establish baseline motor ability:
    - Hammersmith Infant Neurological Exam Part 2 (HINE-2)
    - Hammersmith Functional Motor Scale Expanded (HFMSE)
    - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
    - Motor Function Measure 32 (MFM32)
    - Bayley Scales of Infant and Toddler Development – Third Edition (BSID-III)

Continuation of Therapy

- Medical records (e.g., chart notes, laboratory values) of the most recent (less than 1 month prior to continuation request) assessment by at least one of the following assessments:
    - HINE-2
    - HFMSE
    - CHOP-INTEND
    - MFM32
    - BSID-III
    - For members prescribed Evrysdi due to clinical worsening after receiving gene replacement therapy (e.g., Zolgensma, Itvisma): documentation of the impact of Evrysdi therapy (e.g., impact on motor milestones)

Prescriber Specialties

This medication must be prescribed by or in consultation with a physician who specializes in treatment of spinal muscular atrophy.

Coverage Criteria

Spinal Muscular Atrophy (SMA)[1-6]

Authorization of 12 months may be granted for treatment of SMA when all of the following criteria are met:

- Member has type 1, type 2, or type 3 SMA
- There is genetic documentation of 5q SMA homozygous gene mutation, homozygous gene deletion, or compound heterozygote
- Member is not dependent on either of the following:
    - Invasive ventilation or tracheostomy
    - Use of non-invasive ventilation beyond naps and nighttime sleep

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- Member meets one of the following criteria:
    - Member has not previously received gene replacement therapy for SMA (e.g., Zolgensma, Itvisma), or
    - Member has previously received gene replacement therapy for SMA (e.g., Zolgensma, Itvisma) and has experienced a worsening in clinical status since receiving gene replacement therapy as demonstrated by a decline of minimally clinical important difference from highest score achieved or baseline on one of the following exams (based on member age, motor ability, and specific exam)
        - HINE-2: Decline of at least 2 points on kicking and 1 point on any other milestone (excluding voluntary grasp)
        - HFMSE: Decline of at least 3 points
        - CHOP-INTEND: Decline of at least 4 points
        - MFM32: Decline from baseline
        - BSID-III: Inability to sit without support for more than 5 seconds per item 22 of test
- Member will not use Evrysdi and Spinraza concomitantly
- Member's daily dose will not exceed the following:
    - Members less than 2 months of age: 0.15 mg/kg
    - Members 2 months to less than 2 years of age: 0.2 mg/kg
    - Members 2 years of age and older weighing less than 20 kg: 0.25 mg/kg
    - Members 2 years of age and older weighing 20 kg or more: 5 mg

Continuation of Therapy

Note: Members who were previously established on Evrysdi and subsequently administered gene replacement therapy (e.g., Zolgensma, Itvisma) must meet all requirements in the coverage criteria section prior to re-starting therapy on Evrysdi.

Authorization of 12 months may be granted for continued treatment of SMA when all of the following criteria are met:

- Member has type 1, type 2, or type 3 SMA
- Member is not dependent on either of the following:
    - Invasive ventilation or tracheostomy
    - Use of non-invasive ventilation beyond naps and nighttime sleep
- Submission of medical records (e.g., chart notes, laboratory values) of the most recent (less than 1 month prior to continuation request) assessment documenting a positive clinical response from pretreatment baseline to Evrysdi therapy, as demonstrated by at least one of the following assessments:
    - HINE-2
        - One of the following:

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        - Member exhibited improvement or maintenance of previous improvement of at least a 2-point (or maximal score) increase in ability to kick; or
        - Member exhibited improvement or maintenance of previous improvement of at least a 1-point (or maximal score) increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, standing, or walking) excluding voluntary grasp; and
    - One of the following:
        - Member exhibited improvement or maintenance of previous improvement in more HINE-2 motor milestones than worsening (net positive improvement); or
        - Member achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit or stand unassisted, walk)
- HFMSE
    - One of the following:
        - Member exhibited improvement or maintenance of previous improvement of at least a 3-point increase in score; or
        - Member has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so
- CHOP-INTEND
    - One of the following:
        - Member exhibited improvement or maintenance of previous improvement of at least a 4-point increase in score; or
        - Member has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so
- MFM32
    - Member has experienced an increase in their MFM32 score from baseline and that increase correlates with a clinically significant functional improvement
- BSID-III
    - Member exhibited the ability to sit without support for at least 5 seconds after 12 months of treatment
- Member was prescribed Evrysdi due to clinical worsening after receiving gene replacement therapy (e.g., Zolgensma, Itvisma) and there is documentation of stabilization or improvement in clinical status with Evrysdi therapy (e.g., impact on motor milestones).

- Member will not use Evrysdi and Spinraza concomitantly
- Member's daily dose will not exceed the following:
    - Members less than 2 months of age: 0.15 mg/kg
    - Members 2 months to less than 2 years of age: 0.2 mg/kg
    - Members 2 years of age and older weighing less than 20 kg: 0.25 mg/kg
    - Members 2 years of age and older weighing 20 kg or more: 5 mg

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