

Evrysdi (risdiplam)
Effective 07/01/2025

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange		Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit			<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.			
Contact Information	Medical Benefit Pharmacy Benefit		Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A			

Overview

Spinal muscular atrophy is a genetic disorder characterized by weakness and wasting (atrophy) in muscles used for movement (skeletal muscles). It is caused by a loss of specialized nerve cells, called motor neurons that control muscle movement. SMA is caused by an SMN1 gene that is missing or not working properly.

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

Coverage Guidelines

Authorization may be reviewed for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted for members when ALL the following criteria are met:

1. Documented diagnosis of type 1, type 2, or type 3 SMA
2. Documentation of genetic testing confirming 5q SMA homozygous gene mutation, homozygous gene deletion, or compound heterozygote.
3. Prescribed by or in consultation with a neurologist specializing in the treatment of spinal muscular atrophy
4. Documentation member is not dependent on either of the following:
 - a. Invasive ventilation or tracheostomy
 - b. Use of non-invasive ventilation beyond naps and nighttime sleep
5. Documentation member meets ONE of the following criteria:
 - a. Member has not previously received gene therapy for SMA
 - b. Member has previously received gene therapy for SMA and has experienced a worsening in clinical status since receiving gene therapy as demonstrated by a decline of minimally clinical important difference from highest score achieved on one of the following exams (based on member age and motor ability)
 - i. HINE-2: Decline of at least 2 points on kicking and 1 point on any other milestone (excluding voluntary grasp)
 - ii. HFMSE: Decline of at least 3 points

- iii. CHOP-INTEND: Decline of at least 4 points
- 6. Member will not use Evrysdi and Spinraza concomitantly
- 7. Member's daily dose will not exceed the following:
 - a. Member less than 2 months of age: 0.15 mg/kg
 - b. Members 2 months to less than 2 years of age: 0.2 mg/kg
 - c. Members 2 years of age and older weighing less than 20 kg: 0.25 mg/kg
 - d. Members 2 years of age and older weighing 20 kg or more: 5 mg

Continuation of Therapy

Requests for reauthorization will be approved when the member meets ALL initial criteria AND the following criteria are met:

1. 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:
 - a. HINE-2
 - i. One of the following:
 1. Member exhibited improvement or maintenance of previous improvement of at least a 2 point (or maximal score) increase in ability to kick
 2. 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;
 - ii. One of the following:
 1. Member exhibited improvement or maintenance of previous improvement in more HINE-2 motor milestones than worsening (net positive improvement)
 2. Member achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit or stand unassisted, walk)
 - b. HFMSE
 - i. One of the following:
 1. Member exhibited improvement or maintenance of previous improvement of at least a 3-point increase in score
 2. Member has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so
 - c. CHOP-INTEND
 - i. One of the following:
 1. Member exhibited improvement or maintenance of previous improvement of at least a 4-point increase in score
 2. Member has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so
 - d. MFM32
 - i. Member has experienced an increase in their MFM32 score from baseline and that increase correlates with a clinically significant functional improvement
 - e. Member was prescribed Evrysdi due to clinical worsening after receiving gene therapy and there is documentation of stabilization or improvement in clinical status with Evrysdi therapy (e.g., impact on motor milestones).



Limitations

1. Initial approvals and reauthorizations will be for 12 months.
2. The following quantity limits apply:

Drug Name and Dosage Form	Quantity Limit
Evrysdi 0.75mg/mL (80mL) oral solution	120 mL per 30 days
Evrysdi tablet	30 tablets per 30 days

References

1. Evrysdi (risdiplam) [prescribing information]. South San Francisco, CA: Genentech, Inc; February 2025.

Review History

3/17/2021 – Created and Reviewed at March P&T. Effective 05/01/2021.

04/09/2025 – Reviewed and updated for April P&T. Updated initial criteria to: remove requirement that member is at least 2 years of age and less than 25 years of age at initiation of treatment; require that the request is prescribed by or in consultation with a neurologist specializing in the treatment of spinal muscular atrophy; include dosing for members less than 2 months of age. Added quantity limit for Evrysdi tablet. Effective 07/01/2025.

