UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	202 P 1328-6
Program	Prior Authorization/Notification
Medication	Evrysdi® (risdiplam)
P&T Approval Date	9/2020, 9/2021, 7/2022, 8/2023, 7/2024, 12/2024
Effective Date	3/1/2025

1. Background:

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.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Evrysdi** will be approved based on **all** of the following criteria:

   a. Diagnosis of spinal muscular atrophy (SMA)

   -AND-

   b. Patient is not receiving concomitant chronic survival motor neuron (SMN) modifying therapy [e.g., Spinraza (nusinersen)]

   -AND-

   c. **One** of the following:

      (1) Patient has not previously received gene replacement therapy for the treatment of SMA [e.g., Zolgensma (onasemnogene abeparvovec-xioi)]

      -OR-

      (2) **Both** of the following:

         (a) Patient has previously received gene replacement therapy [e.g., Zolgensma (onasemnogene abeparvovec-xioi)] for the treatment of SMA

         -AND-

         (b) Submission of medical records (e.g., chart notes, laboratory values) documenting a decline from pretreatment baseline status following gene replacement therapy [e.g., Zolgensma (onasemnogene abeparvovec-xioi)] as demonstrated by a decline in one of the following exams:

            i. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)

ii. Hammersmith Infant Neurological Exam Part 2 (HINE-2)
iii. Hammersmith Functional Motor Scale Expanded (HFMSE)
iv. Revised Upper Limb Module (RULM) Test
v. Motor Function Measure 32 (MFM-32) Scale

Authorization will be issued for 12 months.

B. Reauthorization

1. **Evrysdi** will be approved based on **both** of the following criteria:

   a. Documentation of positive clinical response to Evrysdi therapy

   -AND-

   b. Patient is not receiving concomitant chronic survival motor neuron (SMN) modifying therapy [e.g., Spinraza (nusinersen)]

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Medical Necessity and/or Supply limits may be in place.

4. References:

1. Evrysdi [package insert]. South San Francisco, CA: Genentech, Inc; September 2024.

Program	Prior Authorization/Notification – Evrysdi (risdiplam)
Change Control	
9/2020	New program
9/2021	Annual review with no changes to clinical coverage criteria. Updated reference.
7/2022	Updated criteria to align with new labeled indication in patients of all ages. Added state mandate and updated reference.
8/2023	Annual review. Updated reference.
7/2024	Annual review. Updated reference.
12/2024	Added criteria for patients that have documented decline from

	pretreatment baseline status following administration of gene replacement therapy. Updated reference.