UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 2304-4
Program	Prior Authorization/Medical Necessity
Medication	Skyclarys® (omaveloxolone)
P&T Approval Date	5/2023, 5/2024, 5/2025, 5/2026
Effective Date	8/1/2026

1. Background:

Skyclarys (omaveloxolone) is indicated for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older.

2. Coverage Criteria[a]:

A. Initial Authorization

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

   a. Diagnosis of Friedreich's ataxia

   -AND-

   b. Confirmed presence of a mutation in the frataxin (*FXN*) gene

   -AND-

   c. Prescribed by, or in consultation with, **one** of the following:

      (1) Neurologist
      (2) Neurogeneticist
      (3) Physical Medicine and Rehabilitation physician (i.e., physiatrist)

   Authorization will be issued for 12 months.

B. Reauthorization

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

   a. Documentation of positive clinical response to **Skyclarys** therapy

   -AND-

   b. Prescribed by, or in consultation with, **one** of the following:

      (1) Neurologist
      (2) Neurogeneticist
      (3) Physical Medicine and Rehabilitation physician (i.e., physiatrist)

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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.
- Supply limits may be in place.

4. References:

1. Skyclarys [package insert]. Plano, TX: Reata Pharmaceuticals, Inc.; December 2024.

Program	Prior Authorization/Medical Necessity – Skyclarys (omaveloxolone)
Change Control	
5/2023	New program.
5/2024	Annual review with no updates to coverage criteria. Updated references.
5/2025	Annual review with no updates to coverage criteria. Updated reference.
5/2026	Annual review with no changes to coverage criteria.

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