

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2025 P 1412-3
Program	Prior Authorization/Notification
Medication	Skyclarys® (omaveloxolone)
P&T Approval Date	5/2023, 5/2024, 5/2025
Effective Date	8/1/2025

**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<sup>a</sup>:**

**A. Initial Authorization**

1. **Skyclarys** will be approved based on the following criterion:

- a. Diagnosis of Friedreich's ataxia

**Authorization will be issued for 12 months.**

**B. Reauthorization**

1. **Skyclarys** will be approved based on the following criterion:

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

**Authorization will be issued for 12 months.**

<sup>a</sup> 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 and/or Medical Necessity may be in place.

**4. References:**

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

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<b>Change Control</b>	
5/2023	New program.
5/2024	Annual review with no changes to coverage criteria. Updated references.
5/2025	Annual review with no changes to coverage criteria. Updated references.