



UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2024 P 2304-2
Program	Prior Authorization/Medical Necessity
Medication	Skyclarys™ (omaveloxolone)
P&T Approval Date	5/2023, 5/2024
Effective Date	8/1/2024

**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 **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)

**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 may be in place.

**4. References:**

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

Program	Prior Authorization/Medical Necessity – Skyclarys™ (omaveloxolone)
<b>Change Control</b>	
5/2023	New program.
5/2024	Annual review with no updates to coverage criteria. Updated references.