Louisiana Medicaid
Omaveloxolone (Skyclarys™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for omaveloxolone (Skyclarys™).

Additional Point-of-Sale edits may apply.

By submitting the authorization request, the prescriber attests to the conditions available HERE.

Approval Criteria for Initiation of Therapy

- The recipient is 16 years of age or older on the date of the request; **AND**
- The recipient has a diagnosis of Friedreich's ataxia confirmed by genetic testing demonstrating an FXN gene mutation; **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a neurologist; **AND**
- The following is true and is **stated on the request**:
    - The recipient has a baseline modified Friedreich's Ataxia Rating Scale (mFARS) score between 20 and 80 within the previous 30 days; **AND**
    - The recipient has a baseline left ventricular ejection fraction ≥ 40% within the previous 30 days; **AND**
    - The recipient does not have history of clinically significant left-sided heart disease, clinically significant cardiac disease, or pes cavus; **AND**
    - The recipient retains upper limb strength, allowing~~has~~ ambulatory function with minimal assistance (including the use of a cane, crutches, a wheelchair, etc.).

Duration of approval for initiation of therapy: 6 months

Approval Criteria for Continuation of Therapy

- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of approval for continuation of therapy: 12 months

Reference

Skyclarys (omaveloxolone) [package insert]. Plano, TX: Reata Pharmaceuticals, Inc; January 2024. https://www.skyclarys.com/docs/skyclarys_us_prescribing_information/

Revision / Date	Implementation Date
Policy Created / July 2023	January 2024
Formatting changes, updated reference / March 2024	July 2024
Clarification of criterion referring to ambulatory function / August 2024	January 2025