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.

*This agent may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety Regulations. Please refer to individual prescribing information for details.*

Approval Criteria

- 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 has ambulatory function; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of initial approval: 6 months

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**

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

Duration of reauthorization approval: 12 months

Reference

Skyclarys (omaveloxolone) [package insert]. Plano, TX: Reata Pharmaceuticals, Inc; February 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216718Orig1s000lbl.pdf

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