

Applicable Drugs: Skyclarys (omaveloxolone)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 10/25/2023

Date Last Reviewed / Revised 5/11/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

- I. Documented diagnosis of Friedreich's Ataxia and the following criteria A through C are met:
 - A. Documented genetic testing confirmation of mutation in frataxin gene
 - B. Documented baseline modified Friedreich's Ataxia Rating Scale (mFARS) score of 20 to 80
 - C. Baseline labs including LFTs, BNP, and lipid panel
- II. Minimum age requirement: 16 years of age
- III. Skyclarys is prescribed by, or in consultation with, a neurologist, geneticist, or provider specializing in the management of physical medicine and rehabilitation (ie, physiatrist).
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Advanced cardiac disease (LVEF <40%) and/or clinically significant left-sided heart disease
- Severe hepatic impairment (Child-Pugh Class C)
- BNP levels > 200 pg/mL
- Uncontrolled diabetes (HbA1c >11.0%)

OTHER CRITERIA

- If co-administered with strong CYP3A4 Inhibitors, consider avoiding use, or If unable to avoid, reduce dose to 50 mg daily
- If co-administered with moderate CYP3A4 inhibitor, reduce dose to 100 mg daily or 50 mg daily

- Moderate hepatic impairment (Child-Pugh Class B), reduce dose to 100 mg daily or 50 mg daily

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 90 capsules per 30 day

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-authorization:** 12 months with an updated letter of medical necessity or progress notes showing the following:
 - Member retains meaningful voluntary motor function (eg, manipulate objects using upper extremities, ambulates)

APPENDIX

NA

REFERENCES

1. Skyclarys. Package insert. Reata Pharmaceuticals, Inc; 2024. Accessed May 11, 2026. [Skyclarys USPI and PPI clean 04.2026 \(59564-04\) \(1\).pdf](#)
2. Lee A. Omaploxozone: First Approval. *Drugs*. 2023;83(8):725-729. doi: 10.1007/s40265-023-01874-9.
3. Lynch DR, Chin MP, Delatycki MB, Subramony SH, Corti M, Hoyle JC, Boesch S, Nachbauer W, Mariotti C, Mathews KD, Giunti P, Wilmot G, Zesiewicz T, Perlman S, Goldsberry A, O'Grady M, Meyer CJ. Safety and Efficacy of Omaploxozone in Friedreich Ataxia (MOXle Study). *Ann Neurol*. 2021;89(2):212-225. doi: 10.1002/ana.25934.
4. Lynch DR, Chin MP, Boesch S, Delatycki MB, Giunti P, Goldsberry A, Hoyle JC, Mariotti C, Mathews KD, Nachbauer W, O'Grady M, Perlman S, Subramony SH, Wilmot G, Zesiewicz T, Meyer CJ. Efficacy of Omaploxozone in Friedreich's Ataxia: Delayed-Start Analysis of the MOXle Extension. *Mov Disord*. 2023;38(2):313-320. doi: 10.1002/mds.29286.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.