

Generic Name: omaveloxolone

Applicable Drugs: Skyclarys

Preferred: N/A

Non-preferred: N/A

Date of Origin: 10/25/2023

Date Last Reviewed / Revised: 7/29/2024

PRIOR AUTHORIZATION CRITERIA

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

- I. Documented diagnosis of Friedreich's Ataxia an age \geq 16 years of age
- II. Documented genetic testing confirmation of mutation in frataxin gene
- III. Diagnosed by neurologist
- IV. Documented modified Friedreich's Ataxia Rating Scale (mFARS) score of 20-80
- V. Baseline labs including LFTs, BNP, lipid panel

EXCLUSION CRITERIA

- With pes cavus – loss of lateral support
- Advanced cardiac disease

OTHER CRITERIA

- NA

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 90 capsules per 30 day

APPROVAL LENGTH

- **Authorization:** 1 year
- **Re-Authorization:** 1 year with an updated letter of medical necessity or progress notes showing improvement or maintenance with medication with mFARS score documentation
 - Drug safety monitoring has been completed including lipid panel, liver function tests, BNP monitoring

APPENDIX

NA

REFERENCES

1. Skyclarys. Package insert. Reata Pharmaceuticals, Inc; 2024. Accessed July 29, 2024.
2. Lee A. Omaveloxolone: First Approval. *Drugs*. 2023;83(8):725-729.
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 Omaveloxolone in Friedreich Ataxia (MOXle Study). *Ann Neurol*. 2021;89(2):212-225
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 Omaveloxolone in Friedreich's Ataxia: Delayed-Start Analysis of the MOXle Extension. *Mov Disord*. 2023;38(2):313-320.

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.