PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Skyclarys (omaveloxolone)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Skyclarys was initially approved by the FDA in 2023 for Friedreich's ataxia. The exact mechanism by which it works is unknown. Skyclarys has been shown to activate the Nuclear factor (erythroid-derived 2)-like 2 (Nrf2) pathway in vitro and in vivo in animals and humans. The Nrf2 pathway is involved in the cellular response to oxidative stress. Skyclarys is the first FDA approved treatment for Friedreich's ataxia.
Friedreich ataxia is the most common hereditary ataxia. Most cases are caused by loss-of-function mutations in the frataxin (FXN) gene. The majority of patients have an expanded guanine-adenine-adenine (GAA) trinucleotide repeat in both alleles of the FXN gene. Patients with larger GAA expansions have an earlier age at onset, shorter times to loss of ambulation, a greater frequency of cardiomyopathy, and loss of reflexes in the upper limbs.

Skyclarys (omaveloxolone) will be considered for coverage when the following criteria are met:

Friedreich's Ataxia

For **initial** authorization:
1. Member is at least 16 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a diagnosis of Friedreich's ataxia with documentation of the frataxin (FXN) gene mutation confirmed by genetic testing; AND
4. Baseline liver function tests, BNP and lipid parameters have been or will be completed prior to initiation.
5. **Dosage allowed/Quantity limit:** 150 mg orally once daily. Quantity limit: 90 capsules per 30 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show improvement or stabilized signs and symptoms of disease (ex. Improved gait, improved modified Friedreich's Ataxia Rating Scale (mFARS) score, ability to walk, decreased falls etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Skyclarys (omaveloxolone) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/08/2023	New policy for Skyclarys created.

References:

1. Skyclarys. Package insert. Reata Pharmaceuticals Holdings, LLC; 2023.
2. Lynch DR, Chin MP, Delatycki MB, et al. Safety and Efficacy of Omaveloxolone in Friedreich Ataxia (MOXIe Study). Ann Neurol. 2021;89(2):212-225. doi:10.1002/ana.25934
3. Lynch DR, Chin MP, Boesch S, et al. Efficacy of Omaveloxolone in Friedreich's Ataxia: Delayed-Start Analysis of the MOXIe Extension. Mov Disord. 2023;38(2):313-320. doi:10.1002/mds.29286
4. Corben LA, Lynch D, Pandolfo M, Schulz JB, Delatycki MB; Clinical Management Guidelines Writing Group. Consensus clinical management guidelines for Friedreich ataxia. Orphanet J Rare Dis. 2014;9:184. Published 2014 Nov 30. doi:10.1186/s13023-014-0184-7
5. Opal P, Zoghbi HY. Friedreich ataxia. In: UpToDate, Post, TW (Ed), UpToDate, Waltham, MA, 2023.

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