Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	July 14, 2023 May 8, 2024

Skyclarys™ (omaveloxolone)

LENGTH OF AUTHORIZATION: 6 months

REVIEW CRITERIA:

- Patient must be ≥ 16 years of age; **AND**
- Patient must have a diagnosis of Friedreich's ataxia as confirmed by molecular genetic testing and detection of biallelic pathogenic variant in the FXN gene and clinical signs and symptoms (e.g., ataxia, speech disturbance, sensory dysfunction, etc.) that is consistent with Friedreich's ataxia; **AND**
- Patient retains meaningful voluntary motor function (e.g., manipulate objects using upper extremities); **AND**
- Patient does not have a history of clinically significant left-sided heart disease and/or clinically significant cardiac disease (Note: excludes mild to moderate cardiomyopathy associated with Friedreich's ataxia); **AND**
- Patient does not have signs of very advanced disease (e.g., cardiomyopathy by transthoracic echocardiogram); **AND**
- Patient B-Type Natriuretic Peptide (BNP) is ≤ 200 pg/mL prior to initiating therapy and will be monitored periodically during treatment; **AND**
- Prescriber will assess the following prior to therapy initiation and periodically during therapy as recommended in the product label *(documentation required)*:
    - Liver function (alanine transaminase [ALT], aspartate transaminase [AST], bilirubin); **AND**
    - Lipid parameters; **AND**
- Patient does not have severe hepatic impairment (Child-Pugh C); **AND**
- Patients of reproductive potential have been advised to use non-hormonal contraceptive method (e.g., non-hormonal intrauterine system, condoms) during therapy and for 28 days after discontinuation.

CONTINUATION OF THERAPY

- Patient met initial review criteria; **AND**
- Patient must have disease improvement as defined by stabilization OR slowed progression of disease signs and symptoms (e.g., bulbar function, upper/lower limb coordination, upright stability) from pretreatment baseline; **AND**
- Patient has not experienced any treatment-restricting adverse effects (e.g., fluid overload, heart failure; ALT or AST >5x the ULN or >3x the ULN with signs of liver dysfunction) *(liver function test documentation required)*; **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

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DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 50 mg capsule.