

SKYCLARYS (omaveloxolone)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 16 years of age or older

Diagnosis

Patient must have the following:

1. Friedreich's ataxia

AND ALL of the following:

- a. Genetic confirmation of Friedreich's ataxia
- b. Patient exhibits clinical manifestations of disease (e.g., muscle weakness, decline in coordination, frequent falling)
- c. Left ventricular ejection fraction (LVEF) $\ge 40\%$
- d. Prescriber agrees to monitor AST, ALT, and total bilirubin
- e. Prescriber agrees to monitor B-type natriuretic peptide (BNP) and lipid parameters (including LDL)

Prior - Approval Limits

Quantity 270 capsules per 90 days

Duration 12 months

Prior – Approval Renewal Requirements

Age 16 years of age or older

Diagnosis

Patient must have the following:

1. Friedreich's ataxia

AND ALL of the following:

- Patient has had a clinical benefit from therapy (e.g., slowed decline in limb coordination) OR patient has had a reduction in modified Friedreich's Ataxia Rating Scale (mFARS) score of at least 1.5 points from baseline
- b. Prescriber agrees to monitor AST, ALT, and total bilirubin



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c. Prescriber agrees to monitor B-type natriuretic peptide (BNP) and lipid parameters (including LDL)

Prior - Approval Renewal Limits

Same as above