Effective Date: 10/1/2023
Reviewed: 7/23, 6/24, 7/25, 7/26
Pharmacy Scope: Medicaid

SKYCLARYS (omaveloxolone)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Skyclarys is indicated for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Friedreich's Ataxia
Authorization of 6 months may be granted for treatment of Friedreich's ataxia when all of the following criteria are met:

A. The medication must be prescribed by or in consultation with a neurologist or physician who specializes in the treatment of Friedreich's ataxia.
B. Documentation that the member has a diagnosis that is confirmed by detection of a mutation of the *FXN* gene.
C. Documentation that the member exhibits clinical manifestations of disease (e.g., muscle weakness, decline in coordination, frequent falling).
D. Documentation that the member is 16 years of age or older.
E. Documentation that the member is ambulatory

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment of Friedreich's ataxia with documentation that the disease has improved or stabilized (e.g., improvement in speech or swallowing, upper/lower limb coordination, upright stability).

IV. QUANTITY LIMIT

Skyclarys 50mg capsules have a quantity limit of 3 capsules per day.

V. REFERENCES

1. Skyclarys [package insert]. Plano, TX: Reata Pharmaceuticals, Inc.; April 2026.
2. Bidichandani SI, Duncan CG. Friedreich's ataxia - symptoms, causes, treatment: NORD. National Organization for Rare Disorders. https://rarediseases.org/rare-diseases/friedreichs-ataxia/. Published January 25, 2023. Accessed May 24, 2023.