

Effective Date: 10/1/2023
Reviewed: 7/23, 6/24, 7/25
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.; December 2024.
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