

<b>Effective Date: 10/1/2023</b>
Reviewed: 7/23, 6/24
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. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- A. For initial requests:
  - 1. Testing or analysis confirming a mutation of the *FXN* gene
  - 2. Medical record documentation confirming the member demonstrates clinical manifestations of disease (e.g., muscle weakness, decline in coordination, frequent falling)
- B. For continuation requests:
  - 1. Medical record documentation confirming improvement or stabilization of the disease (e.g., improvement in speech or swallowing, upper/lower limb coordination, upright stability).

#### III. 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. The diagnosis is confirmed by detection of a mutation of the *FXN* gene.
- C. Member exhibits clinical manifestations of disease (e.g., muscle weakness, decline in coordination, frequent falling).
- D. Member is 16 years of age or older.
- E. Member is ambulatory

#### IV. CONTINUATION OF THERAPY

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

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## V. QUANTITY LIMIT

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

## VI. REFERENCES

1. Skyclarys [package insert]. Plano, TX: Reata Pharmaceuticals, Inc.; January 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.