

Specialty Guideline Management

Skyclarys

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Skyclarys	omaveloxolone

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 Indications¹

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.

Documentation

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

- Testing or analysis confirming a mutation of the FXN gene.
- Chart notes or medical record documentation confirming the member demonstrates clinical manifestations of disease (e.g., muscle weakness, decline in coordination, frequent falling).

Reference number(s)
5803-A

Prescriber Specialties

This medication must be prescribed by or in consultation with a physician who specializes in the treatment of Friedreich's ataxia or a neurologist.

Coverage Criteria

Friedreich's ataxia¹⁻³

Authorization of 12 months may be granted for treatment of Friedreich's ataxia when all of the following criteria are met:

- The diagnosis is confirmed by detection of a variant of the FXN gene.
- Member exhibits clinical manifestations of disease (e.g., muscle weakness, decline in coordination, frequent falling).
- Member is 16 years of age or older.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section who are experiencing benefit from therapy as evidenced by disease stability or disease improvement (e.g., improvement in speech or swallowing, upper/lower limb coordination, upright stability).

References

1. Skyclarys [package insert]. Cambridge, MA: Biogen; December 2024.
2. Friedreich's ataxia: NORD. National Organization for Rare Disorders. <https://rarediseases.org/rare-diseases/friedreichs-ataxia/>. Last updated October 24, 2023. Accessed February 25, 2025.
3. Friedreich Ataxia: NINDS. National Institute of Neurological Disorders and Stroke. <https://www.ninds.nih.gov/health-information/disorders/friedreich-ataxia>. Last updated July 19, 2024. Accessed February 25, 2025.