



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Skyclarys

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Effective Date: 8/19/2024

Last Review Date: 7/2024

Applies to:	<input checked="" type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input checked="" type="checkbox"/> New Jersey
	<input checked="" type="checkbox"/> Maryland	<input checked="" type="checkbox"/> Florida Kids	<input checked="" type="checkbox"/> Pennsylvania Kids
	<input type="checkbox"/> Michigan	<input checked="" type="checkbox"/> Virginia	

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Skyclarys under the patient's prescription drug benefit.

Description:

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.

Applicable Drug List:

Skyclarys

Policy/Guideline:

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)

Prescriber Specialty:

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

Criteria for Initial Approval:

Friedreich's ataxia

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 mutation 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.



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Continuation of Therapy:

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in criteria for initial approval 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).

Approval Duration and Quantity Restrictions:

Initial and Renewal Approval: 12 months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

References:

1. Skyclarys [package insert]. Cambridge, MA: Reata Pharmaceuticals, Inc.; January 2024.
2. Friedreich's ataxia: NORD. National Organization for Rare Disorders.
<https://rarediseases.org/rare-diseases/friedreichs-ataxia/>. Last updated October 24, 2023.
Accessed March 15, 2024