



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Skyclarys

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Effective Date: 7/6/2023

Last Review Date: 4/12/2023

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:

#### I. DOCUMENTATION

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

##### A. Initial requests:

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

#### II. CRITERIA FOR INITIAL APPROVAL

##### **Friedreich's Ataxia**

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

- A. Skyclarys is prescribed by or in consultation with a 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



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### III. CRITERIA FOR CONTINUATION OF THERAPY

Authorization may be granted for 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).

#### 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]. Plano, TX: Reata Pharmaceuticals, Inc.; February 2023.
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 March 9, 2023.