



Wellmark Blue Cross and Blue Shield is an Independent Licensee of the Blue Cross and Blue Shield Association.

## DRUG POLICY

# Skyclarys (omaveloxolone)

### NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

### BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

### DESCRIPTION

The intent of the Skyclarys (omaveloxolone) policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### FDA-Approved Indications

Skyclarys (omaveloxolone) is indicated for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older.

### POLICY

#### Required Documentation

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

Initial requests:

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

#### Prescriber Specialties

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

#### Criteria for Initial Approval

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

- A. The diagnosis is confirmed by detection of a mutation of the FXN gene
- B. Member exhibits clinical manifestations of disease (e.g., muscle weakness, decline in coordination, frequent falling)
- C. Member is 16 years of age or older
- D. Member has a baseline modified Friedreich's Ataxia Rating Scale (mFARS) score of  $\leq 80$
- E. Patient must be ambulatory

#### Continuation of Therapy

Authorization of 12 months may be granted for continued treatment of Friedreich's ataxia when the member has experienced a positive clinical response to therapy (e.g., slowed disease progression, improvement in or stabilization of speech or swallowing, upper/lower limb coordination, upright stability).

Note: Wellmark reserves the right to confirm a positive clinical response to therapy and clinical records may be requested.

Skyclarys is considered **not medically necessary** for members who do not meet the criteria set forth above.

*Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.*

#### Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

#### Quantity Limits

Skyclarys 50 mg capsules – 3 capsules per day

### PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT\* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

### REFERENCES

- Skyclarys [package insert]. Plano, TX: Reata Pharmaceuticals, Inc.; January 2024.
- 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.

### POLICY HISTORY

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**Revised:**

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