Commercial PA Criteria

Effective: July 6, 2023

Prior Authorization: Skyclarys (omaveloxolone)

Products Affected: Skyclarys (omaveloxolone) oral capsules

Medication Description: SKYCLARYS is indicated for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older. The precise mechanism by which omaveloxolone exerts its therapeutic effect in patients with Friedreich's ataxia is unknown. Omaveloxolone have been shown to activate the Nuclear factor (erythroid-derived 2)-like 2 (Nrf2) pathway in vitro and in vivo in animals and humans. The Nrf2 pathway is involved in the cellular response to oxidative stress

Covered Uses:

1. Friedreich's ataxia

Exclusion Criteria: None

Required Medical Information:

1. Medical history

Prescriber Restriction: Medication is prescribed by or in consultation with a neurologist or a physician who specializes in ataxias and/or neuromuscular disorders

Age Restriction: 16 years and older

Coverage Duration: 12 months

Other Criteria:

Initial Approval Criteria

1. Friedreich's Ataxia.

A. Initial Therapy. Approve if the patient meets ALL of the following (i, ii, iii, iv, v, vi, and vii):

i. Patient is ≥ 16 years of age; **AND**

ii. Patient has had a trinucleotide repeat expansion assay genetic test confirming the diagnosis of Friedreich's ataxia; **AND**

iii. Patient has had ALL of the following in the last year (a, b, and c):

a. Patient has a B-type natriuretic peptide (BNP) ≤ 200 pg/mL; **AND**

b. Patient has a left ventricular ejection fraction ≥ 40%; **AND**

c. Patient has a hemoglobin A_{1c} (HbA_{1c}) ≤ 11% **AND**

iv. Patient has been assessed using the modified Friedreich's Ataxia Rating Scale and has a score ≥ 20, but ≤ 80; **AND**

v. Patient is ambulatory; **AND**

vi. Patient does not have pes cavus; **AND**

vii. Medication is prescribed by or in consultation with a neurologist or a physician who specializes in ataxias and/or neuromuscular disorders.

Renewal Criteria

B. Patient is Currently Receiving Skyclarys. Approve if the patient meets ALL of the following (i, ii, iii, iv and v):
   i. Patient is ≥ 16 years of age; **AND**
   ii. Patient has had genetic testing confirming biallelic pathogenic variants in the frataxin (FXN) gene consistent with a diagnosis of Friedreich's ataxia; **AND**
   iii. Patient is ambulatory; **AND**
   iv. According to the prescriber, the patient continues to benefit from therapy, as demonstrated by a slowed progression on the modified Friedreich's Ataxia Rating Scale; **AND**
   v. The medication is prescribed by or in consultation with a neurologist, or a physician who specializes in ataxias and/or neuromuscular disorders

References:

1. Product Information: Skyclarys™ oral capsules, omaveloxolone oral capsules. Reata Pharmaceuticals, Inc (per FDA), Plano, TX, 2023.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	07/06/2023
2	Update	Updated renewal criteria from ii. Patient has had a trinucleotide repeat expansion assay genetic test confirming the diagnosis of Friedreich's ataxia; to ii. Patient has had genetic testing confirming biallelic pathogenic variants in the frataxin (FXN) gene consistent with a diagnosis of Friedreich's ataxia	Renewal criteria	2/28/2025