



## Commercial/Healthcare Exchange 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  $\geq 16$  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)  $\leq 200$  pg/mL; **AND**
    - b. Patient has a left ventricular ejection fraction  $\geq 40\%$ ; **AND**
    - c. Patient has a hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>)  $\leq 11\%$  **AND**
  - iv. Patient has been assessed using the modified Friedreich's Ataxia Rating Scale and has a score  $\geq 20$ , but  $\leq 80$ ; **AND**

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- 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  $\geq$  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 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

