

<b>Policy Name:</b>	<b>Skyclarys (omaveloxolone)</b>	<b>Policy#:</b>	<b>3195P</b>
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## Purpose of the Policy

The purpose of this policy is to define coverage criteria for Skyclarys (omaveloxolone)

## Statement of the Policy

Health Alliance Medical Plans will approve the use of Skyclarys (omaveloxolone) under the pharmacy benefit if the following criteria are met.

## Criteria

### 1. Coverage Criteria

- 1.1 Documented diagnosis of Friedreich ataxia confirmed by BOTH neuroimaging as well as genetic testing
  - Magnetic resonance imaging (MRI) of the brain and spinal cord are recommended to confirm diagnosis
  - Genetic testing to confirm triplet repeat in the first intron of the frataxin (*FXN*) gene is required
- 1.2 Age 16-40 years old
- 1.3 Prescribed by or in consultation with a neurologist (nervous system doctor)
- 1.4 Documentation of baseline modified Friedreich's Ataxia Rating Scale (mFARS) score of 20-80
- 1.5 Patient is currently able to move independent of mobile aids or able to complete most activities of daily living (ADLs) independently
- 1.6 Clinical review of documentation confirming that patient has met all of the above requirements for treatment completed by both a pharmacist and medical director

### 2. Exclusion Criteria

- 2.1 Evidence of severe pes cavus (foot deformities)
  - Participants in clinical trials with severe pes cavus was limited and clinical improvement in this patient population has not been established
- 2.2 Documentation of severe liver impairment (Child-Pugh C)
- 2.3 Clinically significant heart disease or uncontrolled diabetes

### 3. Managed Dose Limit

- 3.1 90 capsules per 30 days

### 4. Approval Period

- 4.1 Initial: 12 months
- 4.2 Reauthorization: 12 months with documented medical assessment that the disease progression has been slowed or improvement in mFARS

## CPT Codes

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## HCPCS Codes

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## References

1. Skyclarys (omaveloxolone) [prescribing information]. Cambridge, MA: Reata Pharmaceuticals Inc; January 2024.
2. Lynch DR, Chin MP, Delatycki MB, et al. Safety and efficacy of omaveloxolone in Friedreich ataxia (MOXIe Study). *Ann Neurol.* 2021;89 (2):212-225.
3. Lynch DR, Chin MP, Boesch S, et al. Efficacy of Omaveloxolone in Friedreich's Ataxia: Delayed-Start Analysis of the MOXIe Extension. *Mov Disord.* 2023 Feb;38 (2):313-320.
4. Abeti R, Baccaro A, Esteras N, Giunti P. Novel Nrf2-inducer prevents mitochondrial defects and oxidative stress in Friedreich's ataxia models. *Front Cell Neurosci.* 2018; 12:188.

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## DISCLAIMER

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