

Clinical Oversight Review Board (CORB) Criteria for Prescribing/ Criteria-Based Consultation (CBC) Criteria for Coverage

Omaveloxolone (Skyclarys)

Notes:

- Quantity Limits: Yes

Non-Formulary **omaveloxolone (Skyclarys)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria: Non-Formulary **omaveloxolone (Skyclarys)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by a neurologist or geneticist
- Patient has a diagnosis of genetically confirmed Friedreich's ataxia
- Patient is 16 to 40 years old
- Patient has a modified Friedreich's Ataxia Rating Scale (mFARS) score of 20 to 80
- Patient is currently ambulatory and not wheel-chair bound
- Patient has a left ventricular ejection fraction of 40% or higher
- Brain natriuretic peptide (BNP) level of 200 or less
- Patient does NOT have a pes cavus
- Patient has been reviewed by the Kaiser Permanente Interregional Consultative Physician Panel, with recommendation to use medication

Criteria for current Kaiser Permanente members already taking the medication, and for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-Formulary **omaveloxolone (Skyclarys)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by a neurologist or geneticist
- Patient has a diagnosis of genetically confirmed Friedreich's ataxia
- Patient is currently ambulatory and not wheel-chair bound
- Patient is not currently pregnant or breastfeeding
- Patient has been reviewed by the Kaiser Permanente Interregional Consultative Physician Panel, with recommendation to use medication

Continued use criteria for patients previously approved per the above criteria who are currently stable on the medication: Non-Formulary **omaveloxolone (Skyclarys)**

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Revised: 09/14/23
Effective: 11/16/23

All plans offered and underwritten by
Kaiser Foundation Health Plan of the Northwest

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Omaveloxolone (Skyclarys)

will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by a neurologist or geneticist
- Patient is currently ambulatory and not wheel-chair bound
- Patient is not currently pregnant or breastfeeding

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