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| POLICY NAME | Skyclarys (omaveloxolone) | POLICY # | 3195P |
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Criteria

Coverage Criteria

- ☐ 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
- ☐ Age 16-40 years old
- ☐ Prescribed by or in consultation with a neurologist (nervous system doctor)
- ☐ Documentation of baseline modified Friedreich's Ataxia Rating Scale (mFARS) score of 20-80
- ☐ Patient is currently able to move independent of mobile aids or able to complete most activities of daily living (ADLs) independently
- ☐ Clinical review of documentation confirming that patient has met all of the above requirements for treatment completed by both a pharmacist and medical director

Exclusion Criteria – Any of the following prevents coverage

- ☐ 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
- ☐ Documentation of severe liver impairment (Child-Pugh C)
- ☐ Clinically significant heart disease or uncontrolled diabetes