

POLICY NAME

Skyclarys (omaveloxolone)

POLICY #

Criteria

Exclusion Criteria – Any of the following prevents coverage

- ☐ **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

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