SmartPA Criteria Proposal

Drug/Drug Class:	Skyclarys Clinical Edit
First Implementation Date:	TBD
Proposed Date:	October 17, 2023
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☐Revision of Existing Criteria ☒New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Skyclarys™ (omaveloxolone).

Why Issue Selected: On February 28, 2023, the U.S. Food and Drug Administration (FDA) approved Skyclarys™ (omaveloxolone) for the treatment of Friedreich's ataxia (FA) in adults and adolescents ≥ 16 years of age.

FA is a rare, progressive, autosomal recessive genetic neurodegenerative disorder and is one of the most common hereditary ataxias. It primarily affects the function of the cerebellum, spinal cord, and peripheral nervous system. FA can also cause diabetes mellitus, cardiomyopathy, scoliosis, and pes cavus. Pes cavus is a type of foot deformity, where the arch becomes abnormally high due to selective denervation of the leg muscles. The onset of FA is usually between the ages of 10 to 15 years but has been diagnosed in people from the ages of 2 to 50. FA typically is diagnosed before the age of 25. Late-onset FA is characterized by symptom onset after the age of 25 and is found in about 14% of patients diagnosed with FA. In very late-onset FA, symptoms present after the age of 40, however this diagnosis is very rare. Average time from onset to requiring a wheelchair is about 10 to 20 years. More than 95% of patients with FA will become wheelchair bound by 45 years of age. The average lifespan of a patient with FA is about 40 years, with the main cause of death being cardiac dysfunction. The modified Friedreich's Ataxia Rating Scale (mFARS) is a physician-assessed neurologic exam that can be used to track the progression of FA.

Skyclarys is the first treatment available for FA in the United States. There is no cure for FA and there are currently no other pharmacological agents aimed to treat, modify, delay, or prevent the disease. Treatment of FA has historically been supportive and symptomatic in nature.

Due to the high cost and specific approved indication, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Skyclarys.

Program-Specific Information:

Drug	Cost per capsule (WAC)	Cost per month (WAC)*	Cost per year (WAC)*
SKYCLARYS 50 MG CAPSULE	$342.59	$30,833	$369,997

Type of Criteria: ☐ **Increased risk of ADE** ☐ **Preferred Drug List**

	☒ **Appropriate Indications**	☒ **Clinical Edit**
Data Sources:	☐ **Only Administrative Databases**	☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Skyclarys™ (omaveloxolone)
- Age range: All appropriate MO HealthNet participants aged 16 years and older

Approval Criteria

Initial Approval Criteria

- Must meet all of the following:
  - Participant is aged 16 years or older;
  - Prescribed by or in consultation with a neurologist or other specialist in the treated disease state;
  - Participant has a genetically confirmed diagnosis of FA; **AND**
  - Documentation of baseline mFARS score
- Initial approval period: 6 months

Continuation of Therapy

- Must meet all of the following:
  - Documentation of benefit of therapy defined by less than expected decline in disease progression as defined by mFARS score
- Continuation approval period: 12 months

Denial Criteria

- Therapy will deny with presence of one of the following:
  - Any approval criteria are not met; **OR**
  - Participant is currently pregnant

Required Documentation

Laboratory Results:	X	Progress Notes:	X
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
Rule Type: CE

Default Approval Period

6 months

References

- SKYCLARYS™ (omaveloxolone) [package insert]. Plano, TX: Reata Pharmaceuticals, Inc., 2023
- IPD Analytics. New Drug Preview: Omaveloxolone (Omav; RTA 408). Published: August 2022. Accessed: August 7, 2023.

- IPD Analytics. New Drug Review: Skyclarys (omaveloxolone). Published: March 2023. Accessed: August 6, 2023.
- Rare Disease Advisor. Friedreich's Ataxia. https://www.rarediseaseadvisor.com/disease-info-pages/friedreich-ataxia-prognosis/. January 19, 2023. Accessed August 10, 2023.
- GlobeNewswire. Reata Pharmaceuticals, Inc. Announces Positive Data From Part One of Moxie Trial of Omaveloxolone for Friedreich's Ataxia. https://www.globenewswire.com/news-release/2017/06/01/1005786/0/en/Reata-Pharmaceuticals-Inc-Announces-Positive-Data-From-Part-One-of-Moxie-Trial-of-Omaveloxolone-for-Friedreich-s-Ataxia.html. June 1, 2017. Accessed July 28, 2023.
- Opal, Puneet and Zoghbi, Huda. Friedreich Ataxia. UpToDate. https://www.uptodate.com/contents/friedreich-ataxia#H2. March 21, 2023. Accessed July 28, 2023.