ALASKA MEDICAID
Prior Authorization Criteria

Skyclarys™ (omaveloxolone)

FDA INDICATIONS AND USAGE[1]

Skyclarys is indicated for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older.

APPROVAL CRITERIA[1,2]

1. Patient meets FDA labeling approved age **AND**;
2. Prescribed by or in consultation with a neurologist **AND**;
3. Patient has the diagnosis of Friedreich's ataxia **AND**;
4. Patient has a mutation in the frataxin (FXN) gene confirmed by genetic testing **AND**;
5. Patient is clinically symptomatic (e.g. impaired coordination, diminished reflexes, frequent falls, skeletal muscle weakness, etc.) **AND**;
6. Patient has a modified Friedreich's Ataxia Rating Scale score ≥ 20, but ≤ 80 **AND**;
7. Patient has baseline laboratory values within the past year, including LFTs, BNP, HbA_{1C}, and LVEF.

DENIAL CRITERIA [1,2]

1. Failure to meet approval criteria **OR**;
2. Patient has a left ventricular ejection fraction (LVEF) <40% **OR**;
3. Patient has a hemoglobin A_{1C} >11% **OR**;
4. Patient has a B-type natriuretic peptide (BNP) > 200pg/mL **OR;**

CAUTIONS[1]

- Monitor ALT, AST, and total bilirubin prior to initiation, every month for the first three months of treatment, and periodically thereafter
- Avoid concomitant use with moderate or strong CYP3A4 inducers or inhibitors
- May cause fetal harm

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 6 months

QUANTITY LIMIT[1]

- 102 capsules per 34 days

REFERENCES / FOOTNOTES:

1. Skyclarys [prescribing information]. Plano, TX; Reata Pharmaceuticals; February 2023
2. Lynch DR, Chin MP, Delatycki MB et al. Safety and Efficacy of Omaveloxolone in Friedreich Ataxia (MOXIe Study). Ann Neurol. 2021 Feb;89(2):212-225. doi: 10.1002/ana.25934. Epub 2020 Nov 5. PMID: 33068037; PMCID: PMC7894504. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7894504/