

Clinical Policy Title:	omaveloxolone
Policy Number:	RxA.796
Drug(s) Applied:	Skyclarys™
Original Policy Date:	04/13/2023
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Friedreich’s ataxia (must meet all):

1. Diagnosis of Friedreich’s ataxia is confirmed genetically;
2. Member have a modified Friedreich’s ataxia rating scale (mFARS) score ≥ 20 and ≤ 80 .

Approval duration:

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Friedreich’s ataxia (must meet all):

1. Member is currently receiving medication in the past 120 days that has been authorized by RxAdvance or the member has met the initial approval criteria.

Approval duration:

All Lines of Business (except Medicare): 12 months

References

1. Skyclarys. Package insert. Plano, TX. Reata pharmaceuticals. 2024. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=2709e870-df3d-f30f-e063-6394a90aeda1&type=display>. Accessed March 24, 2025.
2. Corben LA, Collins V, Milne S, et al. Clinical management guidelines for Friedreich ataxia: best practice in rare diseases. Orphanet J Rare Dis. 2022;17(1):415. Published 2022 Nov 12. doi:10.1186/s13023-022-02568-3. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9652828/>. Accessed March 24, 2025.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	04/04/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed. <ol style="list-style-type: none"> 1. Removed age and dosing requirements. 2. Removed severe pes cavus and ambulatory requirements. 	4/15/2024	

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<ul style="list-style-type: none"> 3. Increased initial approval duration to 12 months. 4. References were reviewed and updated. 5. Removed reauthorization requirement for positive response to therapy. 		
<p>Policy was reviewed:</p> <ul style="list-style-type: none"> 1. Removed prescriber criteria. 2. Updated continuation of therapy language. 	03/24/2025	04/10/2025
<p>Policy reviewed.</p>	12/11/2025	12/11/2025