=Clinical Policy Title:	omaveloxolone
Policy Number:	RxA.796
Drug(s) Applied:	Skyclarys™
Original Policy Date:	04/13/2023
Last Review Date:	4/15/2024
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. Prescribed by or in consultation with a neurologist.
3. Member have a modified Friedreich's ataxia rating scale (mFARS) score ≥ 20 and ≤ 80;

Initial 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 or has been treated with this medication within the past 90 days;

Initial Approval duration:

All Lines of Business (except Medicare): 12 months

References

1. Skyclarys. Package insert. Plano, TX. Reata pharmaceuticals. 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216718Orig1s000lbl.pdf . Accessed April 12, 2024.
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 April 12, 2024.

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. 1. Removed age and dosing 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.

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2. Removed severe pes cavus and ambulatory requirements. 3. Increased initial approval duration to 12 months. 4. References were reviewed and updated. 5. Removed reauthorization requirement for positive response to therapy.		

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