

Clinical Policy Title:	nitisinone
Policy Number:	RxA.900
Drug(s) Applied:	Harliku
Original Policy Date:	8/1/2025
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Alkaptonuria (AKU) (must meet all):

1. Diagnosis of alkaptonuria
2. Trial and failure for at least 30 days with one of the following (i or ii):
 - i. Nitisinone
 - ii. Nityr

Approval duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Alkaptonuria (AKU) (must meet all):

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

Approval duration

All Lines of Business (except Medicare): 12 months

References

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	8/1/25	N/A
Policy reviewed	12/11/2025	12/11/2025

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.