UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1483-1
Program	Prior Authorization/Notification
Medication	Harliku™ (nitisinone)
P&T Approval Date	8/2025
Effective Date	11/1/2025

1. Background:

Harliku™ (nitisinone) is a hydroxyphenyl-pyruvate dioxygenase inhibitor indicated for the reduction of urine homogentisic acid (HGA) in adult patients with alkaptonuria (AKU).

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Harliku** will be approved based on the following criteria:

   a. Diagnosis of alkaptonuria

   Authorization will be issued for 12 months.

B. Reauthorization

1. **Harliku** will be approved based on the following criterion:

   a. Documentation of positive clinical response [e.g., decreased urinary homogentisic acid (HGA) levels] to Harliku therapy

   Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Harliku [package insert]. Cambridge, United Kingdom: Cycle Pharmaceuticals Ltd.; June 2025.

Program	Prior Authorization/Notification – Harliku (nitisinone)
Change Control	
8/2025	New program