Louisiana Medicaid
Nitisinone (Harliku™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for nitisinone (Harliku™).

Additional Point-of-Sale edits may apply.

By submitting the authorization request, the prescriber attests to the conditions available HERE.

Approval Criteria for Initiation of Therapy

- The recipient has a diagnosis of alkaptonuria (AKU) confirmed by **ONE** of the following:
  - Urinary homogentisic acid (HGA) excretion greater than 0.4 g/24h; **OR**
  - Genetic testing showing a mutation in the homogentisate 1,2 dioxygenase (HGD) gene; **AND**
- The requested medication is prescribed by, or the request states that it is prescribed in consultation with, a provider experienced in the treatment of alkaptonuria (AKU).

Approval Criteria for Continuation of Therapy

- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of approval for initiation and continuation of therapy: 12 months

References

ClinicalTrials.gov. Long-Term Study of Nitisinone to Treat Alkaptonuria. https://clinicaltrials.gov/study/NCT00107783

Harliku (nitisinone) [package insert]. Cambridge, United Kingdom: Cycle Pharmaceuticals Ltd; June 2025. https://harliku.com/wp-content/uploads/2025/07/Harliku-Prescribing-Information-06.25.pdf

Sharabi AF, Goudar RB. Alkaptonuria. [Updated 2023 Aug 8]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK560571/

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