

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Nitisinone tablet (Harliku)

Notes:

- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

Initiation (new start) criteria: Non-formulary **nitisinone tablet (Harliku)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescriber is a geneticist or a metabolic specialist.
- Patient has a diagnosis of alkaptonuria (AKU), evidenced by high levels of homogentisic acid (HGA) in the urine.
- Patient has failed a trial of nitisinone capsule AND nitisinone tablet (Nityr) or patient has an allergy or intolerance* to an inactive ingredient found in both nitisinone capsule AND nitisinone tablet (Nityr), which is not present in nitisinone tablet (Harliku).

Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously: Non-formulary **nitisinone tablet (Harliku)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescriber is a geneticist or a metabolic specialist.
- Patient has a diagnosis of alkaptonuria (AKU), evidenced by high levels of homogentisic acid (HGA) in the urine.
- Patient has failed a trial of nitisinone capsule AND nitisinone tablet (Nityr), or patient has an allergy or intolerance* to an inactive ingredient found in both nitisinone capsule AND nitisinone tablet (Nityr), which is not present in nitisinone tablet (Harliku).

Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary **nitisinone tablet (Harliku)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescriber is a geneticist or a metabolic specialist.
- Patient has a diagnosis of alkaptonuria (AKU), evidenced by high levels of homogentisic acid (HGA) in the urine.
- Patient has failed a trial of nitisinone capsule AND nitisinone tablet (Nityr) or patient has an allergy or intolerance* to an inactive ingredient found in both nitisinone capsule AND nitisinone tablet (Nityr), which is not present in nitisinone tablet (Harliku).

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Continued use criteria (12 months after initiation): Non-formulary **nitisinone tablet (Harliku)** will be covered on the prescription drug benefit when the following criteria are met:

- Prescriber continues to be a geneticist or a metabolic specialist.
- Patient is receiving clinical benefit to nitisinone (Harliku) urine homogentisic acid (HGA) levels