

# 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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## CRITERIA FOR DRUG COVERAGE

### Nitisinone tablet (Harliku)

**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