Criteria-Based Consultation Prescribing Program CRITERIA FOR DRUG COVERAGE

Nitisinone tablet (Nityr)

Notes:

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

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

- Patient has a diagnosis of hereditary tyrosinemia type-1 confirmed by one of following:
 - i. Elevated succinylacetone levels in blood or urine samples
 - ii. DNA testing: mutation in the fumarylacetoacetate hydrolase (FAH) gene
- Nitisinone is used in conjunction with a tyrosine and phenylalanine diet restriction
- Patient has failed a trial of nitisinone capsule (Orfadin) or patient has an allergy or intolerance* to an inactive ingredient not found in nitisinone tablet (Nityr).

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

- Patient has a diagnosis of hereditary tyrosinemia type-1 confirmed by one of following:
 - i. Elevated succinylacetone levels in blood or urine samples
 - ii. DNA testing: mutation in the fumarylacetoacetate hydrolase (FAH) gene
- Nitisinone is used in conjunction with a tyrosine and phenylalanine diet restriction
- Patient has failed a trial of nitisinone capsule (Orfadin) or patient has an allergy or intolerance* to an inactive ingredient not found in nitisinone tablet (Nityr).

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

- Patient has a diagnosis of hereditary tyrosinemia type-1 confirmed by one of following:
 - i. Elevated succinylacetone levels in blood or urine samples
 - ii. DNA testing: mutation in the fumarylacetoacetate hydrolase (FAH) gene
- Nitisinone is used in conjunction with a tyrosine and phenylalanine diet restriction

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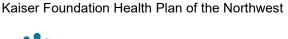
 Patient has failed a trial of nitisinone capsule (Orfadin) or patient has an allergy or intolerance* to an inactive ingredient not found in nitisinone tablet (Nityr).

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

- Patient continues tyrosine and phenylalanine dietary restriction
- Patient is receiving clinical benefit to nitisinone as indicated by decreased
- succinylacetone and alpha-1-microglobulin levels

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