

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Nitisinone capsule (Orfadin)

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 capsule (Orfadin)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- 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

Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously: Non-formulary **nitisinone capsule (Orfadin)** will be covered on the prescription drug benefit for 12 months 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

Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary **nitisinone capsule (Orfadin)** will be covered on the prescription drug benefit for 12 months 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

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Continued use criteria 12 months after initiation: Non-formulary **nitisinone (Orfadin)** will continue to 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