Nitisinone (Orfadin and Nityr)

Initial Authorization Criteria:

1. Prescribed by a metabolic disease specialist; and,
2. Patient has a diagnosis of Hereditary Tyrosinemia Type 1 (HT-1); and,
3. The requested medication is prescribed as an adjunct to dietary restriction of tyrosine and phenylalanine; and,
4. The requested medication will not be used in combination with another nitisinone product; and,
5. Patient has had a documented allergic reaction to generic nitisinone; and,
6. The requested medication is prescribed within the FDA-approved dosing regimen.

Renewal Criteria:

1. Patient has been seen by the prescriber within the previous 12 months; and,
2. Patient shows evidence of positive clinical response on therapy per chart documentation (e.g., decrease in blood and urinary succinylacetone and alpha-1-microglobulin levels); and,
3. Patient continues to be adherent to dietary restriction of tyrosine and phenylalanine; and,
4. Patient has had a documented allergic reaction to generic nitisinone; and,
5. The requested medication is prescribed within the FDA-approved dosing regimen.

Coverage Duration:
Initial and reauthorizations will be provided for 12 months.

P&T Date: August 2016
Effective Date: 11/1/2019; Revised 1/1/2024