Criteria Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE
nitisinone (Orfadin®)

**Initial approval criteria:** Non-formulary nitisinone (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
-AND-

- Nitisinone is used in conjunction with a tyrosine and phenylalanine diet restriction

**Continued use criteria:** Non-formulary nitisinone (Orfadin®) will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Patient continues tyrosine and phenylalanine dietary restriction
  -AND-

- Patient is receiving clinical benefit to nitisinone as indicated by:
  o Decreased succinylacetone and alpha-1-microglobulin levels