PHARMACY POLICY STATEMENT Indiana Medicaid	
DRUG NAME	Orfadin (nitisinone) Preferred Options: Nitisinone 2mg, 5mg, 10mg capsules, Orfadin 20mg capsules, Orfadin 4mg/mL suspension
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior authorization required (Preferred product) QUANTITY LIMIT – 2mg/kg/day
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Orfadin (nitisinone) is a preferred product and will only be considered for coverage under the pharmacy benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

HEREDITARY TYROSINEMIA TYPE 1 (HT-1)

For initial authorization:

1. _____
2. Member must continue a dietary restriction of tyrosine and phenylalanine; AND
3. Chart notes have been provided that show the member has had a positive response (e.g. a reduction in succinylacetone level compared to baseline).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Orfadin (nitisinone) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
04/30/2020	New policy for Orfadin created.