

# PHARMACY POLICY STATEMENT

## Indiana Medicaid

DRUG NAME	Nitisinone (Orfadin and Nityr)
BILLING CODE	Must use valid NDC
BENEFIT TYPE STATUS	Pharmacy

CareSource considers n itisinone not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off- Label policy.

DATE	ACTION/DESCRIPTION
04/30/2020	New policy for Orfadin created.
11/01/2022	Transferred to new template. Renamed policy to generic name and added Nityr brand name. Amended dosing section. Split diagnostic confirmation into 2 parts and added name of mutated gene. Changed wording of slit-lamp exam requirement. Updated references. Added criterion requiring generic caps.

References:

1. Orfadin [prescribing information]. Sobi, Inc; 2021.
2. Nityr [prescribing information]. Cycle Pharmaceuticals Ltd; 2021.
3. Jack RM, Scott CR. Validation of a therapeutic range for nitisinone in patients treated for tyrosinemia type 1 based on reduction of succinylacetone excretion. JIMD reports. 2019;46(1)75-78.
4. Chinsky JM, Singh R, Ficicioglu C, et al. Diagnosis and treatment of tyrosinemia type I: a US and Canadian consensus group review and recommendations. Genet Med. 2017;19(12):. doi:10.1038/gim.2017.101.
5. Sniderman King L, Trahms C, Scott CR. Tyrosinemia Type I. 2006 Jul 24 [Updated 2017 May 25]. In: Adam MP, Everman DB, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2022. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK1515/>

Effective date: 04/01/2023

Revised date: 11/01/2022