

Market Applicability/Effective Date														
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

\*FHK- Florida Healthy Kids

## Orfadin (nitisinone)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	Quantity Limit
Orfadin (nitisinone)	N/A

### APPROVAL CRITERIA

Requests for Orfadin (nitisinone) may be approved for the following indications, when accompanying criteria are met:

- I. Individual has a diagnosis of hereditary tyrosinemia type I (HT-1); **AND**
- II. Individual will be using in combination with a dietary restriction of phenylalanine and tyrosine; **AND**
- III. Individual's plasma tyrosine level is maintained below 500 micromol/L to reduce risk of ocular symptoms, developmental delay, or hyperkeratotic plaques.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A		

### Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2016. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.

DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Drug Facts and Comparisons. Facts and Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; 2016. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2065; Updated periodically.

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

WEB-PEC-0527-16