UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Orfadin

Program	Prior Authorization
Medication	Orfadin® (nitisinone) capsules
Issue Date	5/2016
Pharmacy and Therapeutics Approval Date	10/2017
Effective Date	11/2017

1. Background:

Orfadin (nitisinone) is a synthetic reversible inhibitor of 4-hydroxyphenyl-pyruvate dioxygenase indicated for use as an adjunct to dietary restriction of tyrosine and phenylalanine in the treatment of hereditary tyrosinemia type 1.[1]

NOTE: This policy only applies to Orfadin capsules

2. Coverage Criteria:

A. <u>Authorization</u>

1. **Orfadin capsules** will be approved based on the following criteria:

   a. Diagnosis of hereditary tyrosinemia type 1

Authorization will be issued for 12 months.

3. References:

1. Orfadin [prescribing information]. Waltham, MA. Sobi, Inc. February 2017.

Program	Prior Authorization –Orfadin (nitisinone)
Change Control	
Date	Change
5/2016	New program
2/2017	Added note that policy only applies to Orfadin capsules. Changed reauthorization duration from 24 to 12 months.

5/2017	Added criteria to align with package insert (used as adjunct to diet modification) and updated reauthorization verbiage to align with standard verbiage. Updated references.
9/2017	Removed clinical criteria in addition to diagnosis and removed reauthorization criteria to allow for Dx to Rx implementation