UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Orfadin

Program	Prior Authorization
Medication	Orfadin (nitisinone) capsules, Orfadin (nitisinone) suspension
Markets in Scope	California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	5/2016
Pharmacy and Therapeutics Approval Date	4/2020
Effective Date	6/2020

1. Background:

Orfadin (nitisinone) is a hydroxy-phenylpyruvate dioxygenase inhibitor indicated for the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.

2. Coverage Criteria:

A. Initial Authorization

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

   a. Diagnosis of hereditary tyrosinemia type 1

   -AND-

   b. Prescriber provides a reason or special circumstance the patient cannot use Nityr (nitisinone) tablets

Authorization will be issued for 12 months.

B. Reauthorization

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

   a. Patient shows evidence of positive clinical response (e.g. decrease in urinary/plasma succinylacetone and alpha-1-microglobulin levels) while on Orfadin therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Orfadin [package insert]. Waltham, MA. Sobi, Inc. May 2019.
2. Nityr [package insert]. Cambridge, United Kingdom. Cycle Pharmaceuticals Ltd. November 2018.

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
4/2018	Added step through Nityr for initial authorization. Added reauthorization review criteria. Updated background and references.
4/2019	Annual review. Minor updates to the background. Updated references.
4/2020	Annual review. Updated references.