

### Clinical Pharmacy Program Guidelines for Orfadin

Program	Prior Authorization
Medication	Orfadin <sup>®</sup> (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.<sup>1</sup>

NOTE: This policy only applies to Orfadin capsules

**2. Coverage Criteria:**

A.	<p><b><u>Authorization</u></b></p> <p>1. <b>Orfadin capsules</b> will be approved based on the following criteria:</p> <p style="padding-left: 20px;">a. Diagnosis of hereditary tyrosinemia type 1</p> <p style="text-align: center;"><b>Authorization will be issued for 12 months.</b></p>
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**3. References:**

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

Program	Prior Authorization –Orfadin (nitisinone)
<b>Change Control</b>	
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