



## Commercial/Healthcare Exchange PA Criteria

*Effective: April 27, 2020*

**Prior Authorization:** nitisinone ®

**Products Affected:** Orfadin (nitisinone) 20mg oral capsule, Orfadin (nitisinone) 4mg/mL oral suspension, nitisinone 2mg, 5mg, 10g oral capsules

**Medication Description:** Nitisinone products are hydroxy-phenylpyruvate dioxygenase inhibitors indicated for the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 in combination with dietary restriction of tyrosine and phenylalanine.

**Covered Uses:** Treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.

**Exclusion Criteria:**

1. Concomitant therapy with other nitisinone products (e.g. concomitant therapy with Orfadin, generic nitisinone capsules, and/or Nityr)

**Required Medical Information:**

1. Diagnosis
2. Genetic testing to confirm mutation of FAH gene
3. Serum levels of alpha-fetoprotein (AFP) and succinylacetone

**Age Restrictions:** N/A

**Prescriber Restrictions:** Prescribed by, or in consultation with, a metabolic disease specialist

**Coverage Duration:** 12 months

**Other Criteria:**

- A. Patient has a diagnosis of Hereditary tyrosinemia type 1 (HT-1); AND
- B. Genetic testing confirmed a mutation of the *FAH* gene; AND
- C. The patient has elevated serum levels of alpha-fetoprotein (AFP) and succinylacetone; AND
- D. The medication is prescribed in conjunction with a tyrosine- and phenylalanine-restricted diet

**References:**

1. Orfadin [prescribing information]. Waltham, MA: Sobi, Inc.; May 2019.
2. Nityr [prescribing information]. Cambridge, UK: Cycle Pharmaceuticals; November 2018.

**Policy Revision history**

Last Res. April 2020



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<b>Rev #</b>	<b>Type of Change</b>	<b>Summary of Change</b>	<b>Sections Affected</b>	<b>Date</b>
1	New Policy	New Policy Adopted EH Medicaid Policy	All	4/27/2020