ConnectiCare

Commercial/Healthcare Exchange PA Criteria

Effective: April 27, 2020

Prior Authorization: nitisinone

Products Affected: Orfadin (nitisinone) 20mg oral capsule, Orfadin (nitisinone) 4mg/mLoral suspension, nitisinone 2mg, 5mg, 10mg, 20mg 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

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy Adopted EH Medicaid Policy	All	4/27/2020
2	Update	Added 20mg capsule to products affected	Products Affected	7/24/2023