COMMON GROUND
HEALTHCARE COOPERATIVE

PHARMACY POLICY STATEMENT
Common Ground Healthcare Cooperative (CGHC)

DRUG NAME	**Orfadin (nitisinone)** Preferred Options: Nitisinone 2mg, 5mg, 10mg capsules, Orfadin 20mg capsules, Orfadin 4mg/mL suspension
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required QUANTITY LIMIT – 2mg/kg/day

Orfadin (nitisinone) will be considered for coverage when the following criteria are met:

HEREDITARY TYROSINEMIA TYPE 1 (HT-1)

For **initial** authorization:
If request is for brand name Orfadin 2mg, 5mg, or 10mg capsule strength, please follow policy "Medical Necessity for DAW" on CareSource website.

1. Member has a diagnosis of hereditary tyrosinemia type 1 (HT-1) confirmed by genetic (DNA testing) or biochemical testing (i.e. presence of succinylacetone in the urine or blood); AND
2. Member has a baseline succinylacetone level documented in chart notes; AND
3. Member has an eye exam (e.g. slit-lamp) performed and documented in chart notes prior to initiating treatment; AND
4. Member is using medication in combination with dietary restriction of tyrosine and phenylalanine (commonly found in high-protein food).
5. **Dosage allowed**: up to 1 mg/kg by mouth twice daily.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Member must continue a dietary restriction of tyrosine and phenylalanine; AND
2. Chart notes have been provided that show the member has had a positive response (e.g. a reduction in succinylacetone level compared to baseline).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

DATE	ACTION/DESCRIPTION
04/30/2020	New policy for Orfadin created.
11/19/2021	Annual review, no changes

References:
1. Orfadin [Package Insert]. Waltham, MA: Sobi Inc.; March 2016.
2. Jack RM, Scott CR. Validation of a therapeutic range for nitisinone in patients treated for tyrosinemia type 1 based on reduction of succinylacetone excretion. JIMD reports. 2019;46(1)75-78.
3. Chinsky JM, Singh R, Ficicioglu C, et al. Diagnosis and treatment of tyrosinemia type 1: A US and Canadian consensus group review and recommendations. Genetics in Medicine. 2017;19(12)1380.

Effective date: 01/01/2025
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