PHARMACY POLICY STATEMENT **Georgia Medicaid**	
DRUG NAME	Orfadin (nitisinone) Preferred Options: Nitisinone 2mg, 5mg, 10mg capsules, Orfadin 20mg capsules, Orfadin 4mg/mL suspension
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior authorization required (Preferred product) QUANTITY LIMIT – 2mg/kg/day
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Orfadin (nitisinone) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

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.

CareSource considers Orfadin (nitisinone) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
04/30/2020	New policy for Orfadin created.

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.

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