UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1229-8
Program	Prior Authorization/Notification
Medication	Nityr® (nitisinone)
P&T Approval Date	9/2017, 9/2018, 9/2019, 9/2020, 9/2021, 9/2022, 9/2023, 9/2024
Effective Date	12/1/2024

1. Background:

Nityr® (nitisinone) is a hydroxyphenyl-pyruvate dioxygenase inhibitor indicated for the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Nityr** will be approved based on the following criteria:

   a. Diagnosis of hereditary tyrosinemia type 1

   -AND-

   b. Nityr is being used as an adjunct to diet modification

   Authorization will be issued for 12 months.

B. Reauthorization

1. **Nityr** will be approved based on the following criterion:

   a. Patient shows evidence of positive clinical response (e.g., decrease in urinary/plasma succinylacetone and alpha-1-microglobulin levels) while on Nityr therapy

   Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Supply limits may be in place.

4. References:

1. Nityr [package insert]. Cambridge, United Kingdom. Cycle Pharmaceuticals Ltd.; January 2024.

Program	Prior Authorization/Notification – Nityr (nitisinone) tablets
Change Control	
9/2017	New program
9/2018	Annual review with no changes to coverage criteria.
9/2019	Annual review with no changes to coverage criteria. Updated reference.
9/2020	Annual review with no changes to coverage criteria. Updated reference.
9/2021	Annual review. Changed reauthorization approval duration to 12 months. Updated reference.
9/2022	Annual review with no changes to coverage criteria. Added state mandate disclaimer.
9/2023	Annual review with no changes to coverage criteria. Updated background.
9/2024	Annual review with no changes. Updated reference.