UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3098-8
Program	Step Therapy
Medications	Ravicti® (glycerol phenylbutyrate oral liquid)
P&T Approval Date	7/2017, 7/2018, 2/2019, 2/2020, 2/2021, 2/2022, 2/2023, 2/2024
Effective Date	5/1/2024

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try sodium phenylbutyrate before providing coverage for Ravicti.

Ravicti (glycerol phenylbutyrate) is indicated for chronic management of patients with urea cycle disorders (UCDs) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone. Ravicti must be used with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements).[1]

Sodium phenylbutyrate is indicated as adjunctive therapy in the chronic management of patients with urea cycle disorders. Sodium phenylbutyrate must be used with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements).[2]

Members currently on Ravicti therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

2. Coverage Criteria [a]:

A. Ravicti will be approved based on **one** of the following criteria:

1. History of failure or contraindication to sodium phenylbutyrate

-OR-

2. History of intolerance to sodium phenylbutyrate oral tablets

-OR-

3. **Both** of the following:

   a. Patient is currently on Ravicti therapy

-AND-

   b. Patient has not received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the Horizon Therapeutics sponsored TranscendRare™ program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user

of Ravicti*

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Horizon Therapeutics sponsored TranscendRare™ program shall be required to meet initial authorization criteria as if patient were new to therapy.

Authorization will be granted 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.
- Medical Necessity, Notification, or Supply limits may be in place.

4. References:

1. Ravicti® [package insert], Lake Forest, IL: Horizon Therapeutics, Inc.; September 2021.
2. Buphenyl® [package insert], Scottsdale, AZ: Ucyclyd Pharma, Inc.; March 2023.

Program	Step Therapy – Ravicti
Change Control	
7/2017	New program.
7/2018	Annual review. Updated criteria regarding sodium phenylbutyrate intolerance specifying that patient experience intolerance to oral tablets prior to coverage for Ravicti.
2/2019	Updated background without change to clinical criteria to align with updated indication.
2/2020	Annual review with no change to clinical coverage. Updated reference.
2/2021	Annual review with no change to clinical coverage.
2/2022	Annual review with no change to clinical coverage. Updated references.
2/2023	Annual review with no change to clinical coverage. Updated references.
2/2024	Annual review with no change to clinical coverage. Updated reference.