UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1085-15
Program	Prior Authorization/Notification
Medication	Ravicti® (glycerol phenylbutyrate oral liquid)
P&T Approval Date	04/2013, 4/2014, 4/2015, 2/2016, 12/2016, 12/2017, 12/2018, 2/2019, 2/2020, 2/2021, 2/2022, 2/2023, 2/2024
Effective Date	5/1/2024

1. Background

Ravicti (glycerol phenylbutyrate) is a nitrogen-binding agent 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).

Ravicti is not indicated for treatment of acute hyperammonemia in patients with UCDs. The safety and efficacy for treatment of N-acetylglutamate synthase (NAGS) deficiency has not been established. [1]

Coverage for Ravicti will be provided for patients who meet the following criteria:

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Ravicti** will be approved based on **all** of the following criteria:

   a. Diagnosis of urea cycle disorders (UCDs)

   -AND-

   b. Inadequate response to **one** of the following:

      (1) Dietary protein restriction
      (2) Amino acid supplementation

   -AND-

   c. Will be used concomitantly with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

   Authorization will be issued for 12 months.

B. Reauthorization

1. **Ravicti** will be approved based on **both** of the following criteria:

a. Documentation of positive clinical response to Ravicti therapy

-AND-

b. Patient is actively on dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

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
- Medical Necessity and/or Step Therapy may be in place.

4. References:

1. Ravicti® [package insert], Lake Forest, IL: Horizon Therapeutics, Inc.; September 2021.

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Change Control	
4/2014	Annual review with no change to clinical coverage. Updated reference.
9/2014	Administrative change - Tried/Failed exemption for State of New Jersey removed.
4/2015	Annual review with no change to clinical coverage. Updated background and reference.
2/2016	Annual review with no change to clinical coverage. Updated reference.
12/2016	Annual review. Updated background, formatting and reference.
12/2017	Annual review with no change to clinical coverage. Updated background and reference.
12/2018	Administrative change to add statement regarding use of automated processes.
12/2018	Annual review. No changes to clinical coverage criteria.
2/2019	Updated background and criteria to align with updated indication allowing use in patients less than 2 months of age.
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 reference.
2/2023	Annual review with no change to clinical coverage. Added state mandate footnote.
2/2024	Annual review with no change to clinical coverage.