UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Ravicti

Program	Prior Authorization
Medication	Ravicti™ (glycerol phenylbutyrate oral liquid)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York CHIP, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	6/2013
Pharmacy and Therapeutics Approval Date	2/2021
Effective Date	4/2021

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 in N-acetylglutamate synthase (NAGS) deficiency has not been established.

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

2. Coverage Criteria:

A. <u>Initial Authorization</u>

1. **Ravicti** will be approved based on **<u>all</u>** of the following criteria:

   a. Diagnosis of urea cycle disorders (UCDs)

   -AND-

   b. Inadequate response to **<u>one</u>** 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)

-AND-

d. History of failure, contraindication, or intolerance to sodium phenylbutyrate [Buphenyl] Note: UHC generally does not consider frequency of dosing and/or lack of compliance to dosing regimens an indication of medical necessity

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.

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. Ravicti [package insert]. Lake Forest, IL: Horizon Therapeutics, Inc.; November 2019.

Program	Prior Authorization- Ravicti
Change Control	
Date	Change
6/2013	New drug policy
6/2014	Seperated Ravicti into its own policy. Added the following requirement: • Patient has a contraindication or is not a suitable candidate for sodium phenylbutyrate [Buphenyl]
10/2014	Changed language requiring previous trial of sodium phenylbutyrate and added a clarification that dosing and/or lack of compliance are not generally considered for medical necessity.
11/2016	Annual review, updated policy template
12/2016	Updated background and references.
7/2017	Annual review. No changes.
10/2017	Updated in background and policy that Ravicti is approvable for ages 2 months and older.
7/2018	Annual review. No changes to criteria. Updated reference.
2/2019	Updated background and criteria to reflect expanded age indication. Updated reference.
2/2020	Annual review. Updated reference.
2/2021	Annual review. No changes