

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	April 11, 2013 June 28, 2018, January 18, 2019, October 3, 2019, August 19, 2024

Ravicti® (glycerol phenylbutyrate) oral liquid

LENGTH OF AUTHORIZATION: Initial therapy: 3 months
Continuation of therapy: One year

INITIAL REVIEW:

- Patient must have a diagnosis of urea cycle disorder (UCD).
- Patient must be on dietary protein restriction (verified by supporting documentation).
- Patient must have tried and failed sodium phenylbutyrate (Buphenyl®) oral solution/tablets and sodium phenylbutyrate (Pheburane®) granules as evidenced by unmanaged chronic hyperammonemia over the past 365 days. *(Clinical documentation detailing treatment response must be provided).*
- Medication must be prescribed by a physician experienced in management of UCDs (e.g. geneticist).

CONTINUATION OF THERAPY:

- Patient must continue to meet the above criteria; **AND**
- Documentation of improved clinical response; **AND**
- Patient has not have experienced any treatment-restricting adverse effects; **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING & ADMINISTRATION:

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>
- Available as a 1.1 g/mL oral liquid.