Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	April 11, 2013 June 28, 2018, January 18, 2019, October 3, 2019

RAVICTI® (glycerol phenylbutyrate) oral liquid

LENGTH OF AUTHORIZATION: Initial: THREE MONTHS Continuation: ONE YEAR

REVIEW CRITERIA:

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 Buphenyl (sodium phenylbutyrate) as evidenced by unmanaged chronic hyperammonia over the past 365 days.
- Medication must be prescribed by a physician experienced in management of UCDs (eg. geneticist).

CONTINUATION OF THERAPY:

- Documentation of clinical improvement (verified by supporting documentation).
- Patient continues on dietary protein restriction (verified by supporting documentation).

DOSING & ADMINISTRATION:

- Patients ≥ 2 years of age, the total daily dosage is given in 3 equally divided dosages, rounded up to nearest 0.5 mL.
- Patients < 2 years of age, the total daily dosage is given in 3 or more equally divided dosages, rounded up to nearest 0.1 mL.
- Maximum daily dosage is 17.5 mL (19 g).
- Must be used with dietary protein restriction.

Switching From Sodium Phenylbutyrate to Ravicti:

- Daily dosage of RAVICTI (mL) = daily dosage of sodium phenylbutyrate tablets (g) x 0.86.
- Daily dosage of RAVICTI (mL) = daily dosage of sodium phenylbutyrate powder (g) x 0.81.

Dosage formulation:

- Oral liquid: 1.1 g/mL of glycerol phenylbutyrate.