Sodium phenylbutyrate (Buphenyl, Pheburane, Olpruva)
Glycerol phenylbutyrate (Ravicti)

Coverage Criteria:

1. Prescribed by a metabolic disease specialist; and,
2. Patient has a diagnosis of urea cycle disorder (UCD) that cannot be managed by dietary protein restriction and amino acid supplementation;
3. The requested medication is prescribed as an adjunct to dietary protein restriction and amino acid supplementation; and,
4. For brand drug requests, patient has had a documented allergic reaction to generic sodium phenylbutyrate powder or tablet formulations; and,
5. For Olpruva, patient has had a documented trial and failure of Pheburane; and,
6. For Ravicti, patient has had a documented trial and failure of all of the following:
    a. Pheburane; and,
    b. Olpruva; and,
7. The requested medication is prescribed within the FDA-approved dosing regimen.

Renewal Criteria:

1. Patient has been seen by the prescriber within the previous 12 months; and,
2. Patient continues to be adherent to dietary protein restriction; and,
3. Patient shows evidence of positive clinical response on therapy per chart documentation (e.g., ammonia control and a reduction in the number of hyperammonemic crises); and,
4. Patient has had a documented allergic reaction to generic sodium phenylbutyrate; and,
5. The requested medication is prescribed within the FDA-approved dosing regimen.

Coverage Duration:

Initial approvals will be provided for 6 months.
Reauthorizations will be provided for 12 months.

P&T Date: August 2016;
Effective Date: 1/1/2017; Revised 1/1/24