Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 26, 2024

Olpruva™ (sodium phenylbutyrate) for oral suspension

LENGTH OF AUTHORIZATION: Up to one year

REVIEW CRITERIA:

- Patient must weigh ≥ 20 kg and have a body surface area (BSA) ≥ 1.2 m^2.
- Patient must have a documented diagnosis of urea cycle disorders (UCD) involving deficiencies of any of the following:
  - Carbamylphosphate synthetase (CPS)
  - Ornithine transcarbamylase (OTC)
  - Argininosuccinic acid synthetase (AS)
- Patient must be on dietary protein restriction (verified by supporting documentation).
- Patient had a trial with sodium phenylbutyrate (Buphenyl®) and experienced an inadequate response or intolerance to treatment (clinical documentation must be submitted detailing treatment response).
- Medication is prescribed by or in consultation with a healthcare provider experienced in the treatment of urea cycle disorders.

Note: Olpruva is not indicated for the treatment of acute hyperammonemia.

CONTINUATION OF THERAPY

- Patient met initial review criteria; **AND**
- Documentation of improved clinical response; **AND**
- Patient has not experienced any treatment-restricting adverse effects (i.e., hypokalemia, neurotoxicity, edema, etc.); **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as: 2 g, 3 g, 4 g, 5 g, 6 g, and 6.67 g of sodium phenylbutyrate pellets in packets for reconstitution.