

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	October 14, 2022

### **PHEBURANE® (sodium phenylbutyrate)**

**LENGTH OF AUTHORIZATION:**      Initial: 3 Months  
Continuation: 1 year

**REVIEW CRITERIA:**

- 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 (e.g. geneticist).

**CONTINUATION OF THERAPY:**

- Patient met the above criteria; **AND**
- Documentation of improved clinical response; **AND**
- Patient has not have experienced any treatment-restricting adverse effects; **AND**
- Patient continues on dietary protein restriction (verified by supporting documentation); **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 84 g of sodium phenylbutyrate oral pellets per bottle.