Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	October 14, 2022 November 14, 2024

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).
- 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.