UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1239-6
Program	Prior Authorization/Notification
Medication	Sodium phenylbutyrate (Buphenyl™)
P&T Approval Date	12/2017, 12/2018, 12/2019, 12/2020, 12/2021
Effective Date	3/1/2022; Oxford only: 3/1/2022

1. Background:

Sodium phenylbutyrate (Buphenyl) is indicated as adjunctive therapy in the chronic management of patients with urea cycle disorders involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS). It is indicated in all patients with neonatal-onset deficiency (complete enzymatic deficiency, presenting within the first 28 days of life). It is also indicated in patients with late-onset disease (partial enzymatic deficiency, presenting after the first month of life) who have a history of hyperammonemic encephalopathy. Sodium phenylbutyrate must be used with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements).

Coverage for sodium phenylbutyrate will be provided for patients who meet the following criteria:

2. Coverage Criteria:

A. <u>Initial Authorization</u>

1. **Sodium phenylbutyrate** will be approved based on **<u>both</u>** of the following criteria:

   a. Diagnosis of urea cycle disorders (UCDs)

   -AND-

   b. Will be used concomitantly with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

Authorization will be issued for 12 months.

B. <u>Reauthorization</u>

1. **Sodium phenylbutyrate** will be approved based on **<u>both</u>** of the following criteria:

a. Documentation of positive clinical response to sodium phenylbutyrate therapy

-AND-

b. Patient is actively on dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits may be in place

4. References:

1. Buphenyl® [package insert], Lake Forest, IL: Horizon Therapeutics, Inc.; April 2008.

Program	Prior Authorization/Notification – Sodium phenylbutyrate (Buphenyl)
Change Control	
12/2017	New program
12/2018	Administrative change to add statement regarding use of automated processes.
12/2018	Annual review. No changes to clinical coverage criteria.
12/2019	Annual review. No changes to clinical coverage criteria.
12/2020	Annual review. No changes to clinical coverage criteria.
12/2021	Annual review. No changes to clinical coverage criteria.