UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1239-9
Program	Prior Authorization/Notification
Medication	Buphenyl® (sodium phenylbutyrate), Olpruva™* (sodium phenylbutyrate), Pheburane®* (sodium phenylbutyrate), sodium phenylbutyrate
P&T Approval Date	12/2017, 12/2018, 12/2019, 12/2020, 12/2021, 12/2022, 12/2023, 2/2024
Effective Date	5/1/2024

1. Background:
Sodium phenylbutyrate is indicated as adjunctive therapy in the chronic management of patients with urea cycle disorders involving deficiencies of carbamoyl phosphate 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).

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Buphenyl, Olpruva*, Pheburane*, or sodium phenylbutyrate** will be approved based on **both** 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. Reauthorization

1. **Buphenyl, Olpruva*, Pheburane*, or sodium phenylbutyrate** will be approved based on **both** of the following criteria:

   a. Documentation of positive clinical response to 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.** [a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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
- Olpruva* brand pellets for oral suspension and Pheburane* brand oral pellets are typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

4. References:

1. Buphenyl® [package insert]. Deerfield, IL: Horizon Therapeutics, Inc.; March 2023.
2. Olpruva™ [package insert]. Newton, MA: Acer Therapeutics, Inc.; December 2022.
3. Pheburane® [package insert]. Princeton, NJ: Medunik USA, Inc.; August 2023

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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.
12/2022	Annual review. No changes to clinical coverage criteria. Added state mandate and updated reference.
12/2023	Annual review. No changes to clinical coverage criteria. Updated reference.
2/2024	Added Olpruva and Pheburane, including statement that Olpruva and Pheburane are typically excluded from coverage. Updated references.