UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Buphenyl

Program	Prior Authorization
Medication	Buphenyl (sodium phenylbutyrate) powder for oral solution, Buphenyl (sodium phenylbutyrate) tablets
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	5/2016
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

1. Background:

Buphenyl is indicated as adjunctive therapy in the chronic management of patients with urea cycle disorders (UCDs). It must be combined with dietary protein restriction with or without essential amino acid supplementation. Buphenyl is indicated in all patients with neonatal-onset deficiency (complete enzymatic deficiency, presenting with 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. Buphenyl should not be used in the management of acute hyperammonemia.

2. Coverage Criteria:

A. <u>Powder for Oral Solution</u>

1. Diagnosis of urea cycle disorders (UCDs)

Authorization will be issued for 12 months.

B. <u>Tablets</u>

1. **<u>Initial Authorization</u>**

a. Diagnosis of urea cycle disorders (UCDs)

-AND-

b. Prescriber provides a reason or special circumstance the patient cannot use Buphenyl (sodium phenylbutyrate) powder for oral solution

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Documentation of positive clinical response to Buphenyl (sodium phenylbutyrate) tablets

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 Prescribing Information. Horizon Therapeutics; Lake Forest, IL.March 2020.

Program	Program type – Prior Authorization
Change Control	
Date	Change
5/2016	New Program
7/2016	Auto-update: Applicable to only oral solution.
7/2017	Updated policy template. Updated background and template.
9/2018	Annual review. Added Buphenyl tablets and review criteria to the policy. Updated background and references.
9/2019	Annual review. Updated backround and references.
9/2020	Annual review. Updated reference.