SODIUM PHENYLBUTYRATE

Generic	Brand	HICL	GCN	Exception/Other
SODIUM PHENYLBUTYRATE	BUPHENYL		43370 43371	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) and meet **ALL** of the following criteria?
   - Documentation of confirmation of UCD via enzymatic, biochemical or genetic testing
   - Physician attestation of **ALL** the following:
     - o Buphenyl will be used as adjunctive therapy along with dietary protein restriction
     - o The patient cannot be managed by dietary protein restriction and/or amino acid supplementation alone

   If yes, **approve the requested agent for 12 months by GPID with a quantity limit:**
   - **Oral tablet: #40 tablets per day.**
   - **Oral powder: #750 grams per 30 days.**

   APPROVAL TEXT: Renewal requires physician attestation of clinical benefit from baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, or mental status clarity).

   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **SODIUM PHENYLBUTYRATE (Buphenyl)** requires a diagnosis of a urea cycle disorder (UCD). In addition, the following criteria must be met:
   - Documentation of confirmation of UCD via enzymatic, biochemical or genetic testing
   - Physician attestation of **ALL** the following:
     - o Buphenyl will be used as adjunctive therapy along with dietary protein restriction
     - o The patient cannot be managed by dietary protein restriction and/or amino acid supplementation alone

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SODIUM PHENYLBUTYRATE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) and meet the following criterion?
   - Physician attestation of clinical benefit from baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, or mental status clarity)

   If yes, **approve the requested agent for 12 months by GPID with a quantity limit:**
   - **Oral tablet: #40 tablets per day.**
   - **Oral powder: #750 grams per 30 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **SODIUM PHENYLBUTYRATE (Buphenyl)** requires a diagnosis of urea cycle disorder (UCD) and physician attestation of clinical benefit from baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, or mental status clarity).

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Buphenyl.

REFERENCES

- Buphenyl [Prescribing Information]. Lake Forest, IL: Horizon Pharma USA, Inc.; November 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/19
Created: 08/19
Client Approval: 08/19
P&T Approval: 07/19