STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM PHENYLBUTYRATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SODIUM PHENYLBUTYRATE	BUPHENYL, PHEBURANE, OLPRUVA, SODIUM PHENYLBUTYRATE	11317		GPI-14 (3090806000)	ROUTE = ORAL

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?
   - There is documentation (e.g., chart notes, lab results, diagnostic test results, etc.) of confirmation of UCD via enzymatic, biochemical or genetic testing
   - The requested medication will be used as adjunctive therapy along with dietary protein restriction
   - The patient cannot be managed by dietary protein restriction or amino acid supplementation alone

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for Buphenyl (sodium phenylbutyrate)?

   If yes, **approve the requested formulation for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Buphenyl tablets: #40 per day.**
   - **Buphenyl powder: #25 grams per day.**

   If no, continue to #3.

3. Is the request for Pheburane, and the patient meets **ALL** of the following criteria?
   - The patient had a trial of or contraindication to generic sodium phenylbutyrate powder
   - The patient is unable to swallow Buphenyl (sodium phenylbutyrate) tablet

   If yes, **approve Pheburane for 12 months by GPID or GPI-14 with a quantity limit of #20 grams per day.**

   If no, continue to #4.

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SODIUM PHENYLBUTYRATE

INITIAL CRITERIA (CONTINUED)

4. Is the request for Olpruva, and the patient meets **ALL** of the following criteria?
   - The patient had a trial of or contraindication to generic sodium phenylbutyrate powder
   - The patient is unable to swallow Buphenyl (sodium phenylbutyrate) tablet

   If yes, **approve the requested strength of Olpruva for 12 months by GPID or GPI-14 as follows:**
   - **2 grams: #12 per day.**
   - **3 grams: #12 per day.**
   - **4 grams: #15 per day.**
   - **5 grams: #12 per day.**
   - **6 grams: #9 per day.**
   - **6.67 grams: #9 per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SODIUM PHENYLBUTYRATE (Buphenyl, Pheburane, Olpruva)** requires the following rule(s) be met for approval:
   A. You have a urea cycle disorder (a genetic disorder that causes high ammonia levels in the blood)
   B. There is documentation (such as chart notes, lab results, diagnostic test results) confirming you have a urea cycle disorder via enzymatic, biochemical or genetic testing (types of lab tests)
   C. The requested medication will be used as adjunctive (add-on) therapy along with dietary protein restriction
   D. Your condition cannot be managed by dietary protein restriction or amino acid supplementation alone
   E. **If your request is for Pheburane or Olpruva, approval also requires:**
      1. You have tried or have a contraindication (harmful for) to generic sodium phenylbutyrate powder
      2. You are unable to swallow Buphenyl (sodium phenylbutyrate) tablet

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SODIUM PHENYLBUTYRATE

RENEWAL CRITERIA

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

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the request for Buphenyl or Pheburane?

   If yes, **approve the requested medication for 12 months by GPID or GPI-14 as follows:**
   - **Buphenyl tablet: #40 per day.**
   - **Buphenyl powder: #25 grams per day.**
   - **Pheburane: #20 grams per day.**

   If no, continue to #3.

3. Is the request for Olpruva?

   If yes, **approve the requested strength of Olpruva for 12 months by GPID or GPI-14 as follows:**
   - **2 grams: #12 per day.**
   - **3 grams: #12 per day.**
   - **4 grams: #15 per day.**
   - **5 grams: #12 per day.**
   - **6 grams: #9 per day.**
   - **6.67 grams: #9 per day.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SODIUM PHENYLBUTYRATE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SODIUM PHENYLBUTYRATE (Buphenyl, Pheburane, Olpruva)** requires the following rule(s) be met for renewal:

A. You have a urea cycle disorder (a genetic disorder that causes high ammonia levels in the blood)
B. You have experienced a clinical benefit from baseline (for example you have normal fasting glutamine levels, low-normal fasting ammonia levels, mental status clarity)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

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

REFERENCES

- Buphenyl [Prescribing Information]. Deerfield, IL: Horizon Therapeutics USA, Inc.; April 2023.
- Olpruva [Prescribing Information]. Newton, MA: Acer Therapeutics Inc.; December 2022.
- Pheburane [Prescribing Information]. Bryn Mawr, PA: Medunik USA, Inc.; June 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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