



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLYCEROL PHENYLBUTYRATE

Generic	Brand	HICL	GCN	Exception/Other
GLYCEROL PHENYLBUTYRATE	RAVICTI	39990		

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
 - The patient is 2 months of age or older
 - Physician attestation of **ALL** the following:
 - Ravicti will be used as adjunctive therapy along with dietary protein restriction
 - The disorder cannot be managed by dietary protein restriction and/or amino acid supplementation alone
 - The patient does **NOT** have a deficiency of N-acetylglutamate synthetase deficiency (NAGS) or acute hyperammonemia
 - The patient has tried or has a contraindication to Buphenyl (sodium phenylbutyrate)

If yes, **approve for 12 months by HICL with a quantity limit of #17.5mL per day.**

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 **GLYCEROL PHENYLBUTYRATE (Ravicti)** 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
- The patient is 2 months of age or older
- Physician attestation of **ALL** the following:
 - Ravicti will be used as adjunctive therapy along with dietary protein restriction
 - The disorder cannot be managed by dietary protein restriction and/or amino acid supplementation alone
- The patient does **NOT** have a deficiency of N-acetylglutamate synthetase deficiency (NAGS) or acute hyperammonemia
- The patient has tried or has a contraindication to Buphenyl (sodium phenylbutyrate)

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GLYCEROL 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 for 12 months by HICL with a quantity limit of #17.5mL per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **GLYCEROL PHENYLBUTYRATE (Ravicti)** requires a diagnosis of a 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 Ravicti.

REFERENCES

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

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/19

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P&T Approval: 07/19