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
Created: 02/13
Client Approval: 08/19
P&T Approval: 07/19