

**HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES**

GLYCEROL PHENYLBUTYRATE (RAVICTI)

Generic	Brand	HICL	GCN	Exception/Other
GLYCEROL PHENYLBUTYRATE	RAVICTI	39990		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has the requested medication been prescribed by, or in consultation with, a specialist in the management of urea cycle disorders (UCDs)?

If yes, continue to #2.

If no, do not approve. Please use status code #238 and the provided denial text:

DENIAL TEXT: Per your health plan's **RAVICTI (glycerol phenylbutyrate)** guideline, this medication is only covered when prescribed by (or in consultation with) a specialist in the management of urea cycle disorders (UCDs). Your provider did not indicate they are a specialist, or is in consultation with a specialist, and therefore your request was not approved.

2. Does the request meet **ALL** of the following conditions?

- Diagnosis of a urea cycle disorder
- Patient tried and failed a protein restricted diet and amino acid supplementation
- Patient tried and failed therapy with sodium phenylbutyrate (Buphenyl)
- Ravicti will be use concomitantly with dietary protein restriction

If yes, **approve by HICL for 12 months**. Please use status code #057 and the approval text provided.

APPROVAL TEXT: Your request for Ravicti has been approved for a 12-month period.

If no, do not approve. Please use status code #238 and the denial text provided.

DENIAL TEXT: Per your health plan's **RAVICTI (glycerol phenylbutyrate)** guideline, this medication is only covered if you meet all of the following conditions:

- Diagnosis of a urea cycle disorder
- You tried and failed a protein restricted diet and amino acid supplementation
- You tried and failed a course of therapy with sodium phenylbutyrate (Buphenyl)
- Ravicti will be use concomitantly with dietary protein restriction

Your provider did not submit information that you [**criteria not met**], and therefore your request was not approved.

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GLYCEROL PHENYL BUTYRATE (RAVICTI)

RENEWAL CRITERIA

1. Has the provider indicated each of the following?
 - Patient experienced an improvement while on therapy AND
 - Patient is on a protein restricted diet

If yes, **approve by HICL for 12 months.** Please use status code #057.

APPROVAL TEXT: Your request for Ravicti has been approved for a 12-month period.

If no, do not approve.

DENIAL TEXT: Per your health plan's **RAVICTI (glycerol phenylbutyrate)** guideline, authorization for renewal requires documentation that your condition has improved while on therapy and that you are on a protein restricted diet. Your provider did not indicate **[criteria not met]** and therefore your request was not approved.

RATIONALE

To promote the appropriate use of Ravicti.

FDA APPROVED INDICATIONS

Ravicti is indicated for chronic management of patients 2 months of age and older with urea cycle disorders (UCDs) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone. RAVICTI must be used with dietary protein restriction and, in some cases, dietary supplements.

REFERENCES

- Ravicti (glycerol phenylbutyrate) [prescribing information]. Lake Forest, IL. Horizon Therapeutics, LLC. April 2017.

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P&T Approval: 12/03/18