

Ravicti (glycerol phenylbutyrate)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Ravicti (glycerol phenylbutyrate) Oral Liquid	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Ravicti (glycerol phenylbutyrate) may be approved when the following criteria are met:

- I. Individual is using for chronic management of a urea cycle disorder (UCD); **AND**
- II. Disorder cannot be managed by dietary protein restriction and/or amino acid supplementation alone; **AND**
- III. Individual is using as adjunctive therapy with dietary protein restriction and, in some cases, dietary supplements, including but not limited to the following:
 - A. Essential amino acids; **OR**
 - B. Arginine; **OR**
 - C. Citrulline; **OR**
 - D. Protein-free calorie supplements.

Continuation requests for Ravicti (glycerol phenylbutyrate) may be approved if the following criteria are met:

- I. Documentation is provided that there is clinically significant improvement or stabilization in plasma ammonia level; **AND**
- II. Use in combination with dietary protein restriction.

Requests for Ravicti (glycerol phenylbutyrate) may **not** be approved for the following:

- I. Management of acute hyperammonemia; **OR**
- II. Using to treat N-acetylglutamate synthase deficiency (NAGS); **OR**
- III. Use in combination with sodium phenylbutyrate (Buphenyl, Pheburane).

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: December 9, 2022.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Haberle J, Boddaert N, Burlina A, et al. Suggested guidelines for the diagnosis and management of urea cycle disorders. *Orphanet J Rare Dis*. 2012;7.

4. Lee B. Urea cycle disorders: Management. Last updated: August 6, 2021. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: December 9, 2022.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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