

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

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

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

- I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one preferred agent;

Preferred agents: generic sodium phenylbutyrate powder or tablets*

AND

- II. Individual is using for chronic management of a urea cycle disorder (UCD); **AND**
- III. Disorder cannot be managed by dietary protein restriction and/or amino acid supplementation alone; **AND**
- IV. 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.

OR

- VI. Ravicti may be approved if the individual has congestive heart failure, severe renal insufficiency, or a clinical state where there is sodium retention with edema;

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

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

CRX-ALL-0383-19

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- I. Management of acute hyperammonemia; **OR**
- II. Using to treat N-acetylglutamate synthase deficiency (NAGS).

*prior authorization may be required

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: November 7, 2018.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. Haberle J, Boddaert N, et al. Suggested guidelines for the diagnosis and management of urea cycle disorders. Orphanet J Rare Dis. 2012;7:1-65.

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