JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS130
		Effective Date	01/20/2021
		Review Date	01/20/2021
	Subject **Ravicti**	*Revision Date*	12/08/2021
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Ravicti

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I. POLICY

A. Ravicti (glycerol phenylbutyrate) oral liquid will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Ravicti** may be approved for patients meeting all the following:
   1. Chronic management of an urea cycle disorders (UCD)
      a. Documentation showing:
         I. Diagnosis of an urea cycle disorder, which has been confirmed through enzymatic, biochemical, or genetic testing
         II. Previous use and ineffectiveness of dietary protein restriction and/or amino acid supplementation alone
         III. Ravicti will be used with dietary protein restriction and in some cases, dietary supplements

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial therapy may be approved for 12 months
B. Continuation of therapy may be approved in 12-month intervals with documentation showing the patient has had a beneficial response to treatment, evidenced by a reduction in plasma ammonia levels from baseline

IV. EXCLUSIONS

A. Ravicti will not be approved for the following:
   1. Treatment of acute hyperammonemia in patients with UCDs as a more rapidly acting intervention is required to reduce plasma ammonia levels in these cases
   2. Treatment of N-acetylglutamate synthase (NAGS) deficiency
   3. Any indications or uses that are not FDA-approved, or guideline-supported

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Ravicti [prescribing information]. Lake Forest, IL: Horizon Pharma USA, Inc.; September 2021.
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VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
01/20/2021	Policy Creation
12/08/2021	Updated Exclusions section regarding physician samples

Review Date: 01/20/2021

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