

Policy Name:	Ravicti (glycerol phenylbutyrate)	Policy#:	3179P
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Purpose of the Policy

The purpose of this policy is to define coverage criteria for Ravicti (glycerol phenylbutyrate).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Ravicti (glycerol phenylbutyrate) under the specialty pharmacy benefit if the following criteria are met.

Criteria

1. Coverage Criteria for Urea Cycle Disorders

- 1.1 Diagnosis of chronic disorder of the urea cycle confirmed by enzymatic, biochemical, or genetic testing
- 1.2 Age 2 months or older
- 1.3 Prescribed by or in consultation with a gastroenterologist (stomach doctor)
- 1.4 Documented trial and failure of dietary protein restriction and/or amino acid supplementation
 - Documentation of ongoing dietary protein restriction and supplementation
- 1.5 Documented trial and failure, intolerance or contraindication to sodium phenylbutyrate (Buphenyl)

2. Approval Period

- 2.1 Initial: 12 months
- 2.2 Reauthorization: 12 months with documented improvement on therapy

CPT Codes

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HCPCS Codes

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References

1. Ravicti (glycerol phenylbutyrate) [prescribing information]. Lake Forest, IL: Horizon Therapeutics USA Inc; September 2021.
2. Berry SA, Longo N, Diaz GA, et al. Safety and efficacy of glycerol phenylbutyrate for management of urea cycle disorders in patients aged 2months to 2years. Mol Genet Metab 2017; 122:46.
3. Smith W, Diaz GA, Lichter-Konecki U, et al. Ammonia control in children ages 2 months through 5 years with urea cycle disorders: comparison of sodium phenylbutyrate and glycerol phenylbutyrate. J Pediatr 2013; 162:1228.
4. Haberle J, Burlina A, Chakrapani A, et al. Suggested guidelines for the diagnosis and management of urea cycle disorders: First revision. J Inherit Metab Dis. 2019 Nov;42(6):1192-1230.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.