Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Ravicti (glycerol phenylbutyrate)

Effective: July 14, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Ravicti (glycerol phenylbutyrate) is indicated as a nitrogen-binding agent for the chronic management of patients with urea cycle disorders (UCDs) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone.

Ravicti (glycerol phenylbutyrate) must be used with dietary protein restriction, and, in some cases, dietary supplements (e.g. essential amino acids, arginine, citrulline, protein-free calorie supplements).

Ravicti (glycerol phenylbutyrate) is not indicated for treatment of acute hyperammonemia in patients with UCDs. The safety and efficacy of Ravicti (glycerol phenylbutyrate) for treatment of N-acetylglutamate synthase deficiency has not been established.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Ravicti (glycerol phenylbutyrate) for patients when **ALL** of the following criteria are met:

1. Documented diagnosis of a urea cycle disorder confirmed by enzymatic, biochemical, or genetic testing

AND

2. Documentation the patient's condition cannot be managed by dietary protein restriction and/or amino acid supplementation alone

AND

3. Documentation the requested medication will be used as an adjunct to a protein-restricted diet

AND

4. Documentation of **ONE** (1) of the following:
    a. Inadequate response to generic Buphenyl at optimized doses
    b. Inability to tolerate a therapeutic dose of generic Buphenyl due to palatability

Limitations

- For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Berry SA, Lichter-Konecki U, Diaz GA, et al. Glycerol phenylbutyrate treatment in children with urea cycle disorders: Pooled analysis of short and long-term ammonia control and outcomes. *Mol Genet Metab*. 2014 Feb 21. pii: S1096-7192(14)00071-7
2. Ravicti (glycerol phenylbutyrate) [prescribing information]. Deerfield, IL: Horizon Therapeutics, LLC.; September 2025.
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 Jun;162(6):1228-34.

Approval And Revision History

September 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- July 11, 2023: no changes
- July 9, 2024: no changes
- January 14, 2025: Added confirmation of a diagnosis of UCD by enzymatic, biochemical or genetic testing. Added the requirement that the requested medication will be used as an adjunct to a protein-restricted diet. Updated the step through generic Buphenyl to require either an inadequate response at optimized doses or palatability issues (eff 4/1/25).
- July 8, 2025: No changes.
- July 14, 2026: Administrative update to remove CareLink from the Medical Necessity Guideline template.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.