Pharmacy Medical Necessity Guidelines: Ravicti® (glycerol phenylbutyrate)

Effective: May 12, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-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 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 is not indicated for treatment of acute hyperammonemia in patients with UCDs, as more rapidly acting interventions are needed to reduce the plasma ammonia levels. The safety and efficacy of Ravicti for treatment of N-acetylglutamate synthase (NAGS) deficiency has not been established.

COVERAGE GUIDELINES

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

1. Documented diagnosis of a urea cycle disorder

AND

2. The Member's condition cannot be managed by dietary protein restriction and/or amino acid supplementation alone

LIMITATIONS

None

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]. Lake Forest, IL: Horizon Therapeutics, LLC.; November 2019.
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 HISTORY

April 12, 2016: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template
2. November 14, 2017: Updated criteria to allow use in patients 2 months and older.
3. November 13, 2018: Administrative changes made to template.
4. August 13, 2019: Removed age restriction from criteria.
5. May 12, 2020: No changes.

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.