Effective Date: 7/1/2020
Last Reviewed: 4/2020, 2/2021, 2/2022 Scope: Medicaid

Ravicti
(Glycerol Phenylbutyrate oral liquid)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Adjunctive treatment to 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.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR APPROVAL

A. Urea Cycle Disorder involving deficiencies of CPS, OTC, or AS

An authorization may be granted for 6 months when the following criteria are met:

1. Prescribed dose does not exceed 19 grams/day.
2. Documentation of urea cycle disorder as evidenced by a lab value of fasting ammonia level > 0.5 Upper Limit of Normal OR a glutamine level that is > 1,000 µmol/L.
3. Diagnosis is confirmed by enzymatic, biochemical, or genetic testing
4. Member must have had an inadequate response to and continue to be on a protein restricted diet or amino acid supplementation.
5. Member had an inadequate response to and cannot tolerate Buphenyl (Sodium Phenylbutyrate).
6. Should not be used for the management of acute hyperammonemia. Prescribed dose does not exceed 19 grams/day.

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for chronic management of a urea cycle disorder (UCD), who are experiencing benefit from therapy as evidenced by a reduction in plasma ammonia levels from baseline.

IV. REFERENCES

1. Ravicti (glycerol phenylbutyrate). Horizon Therapeutics. Lake Forest, IL. FDA Package Insert. September 2021.

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