Effective Date: 7/1/2020
Last Reviewed: 4/2020, 2/2021, 2/2022, 7/2023, 4/2024 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
Ravicti is indicated 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.

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

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. Initial requests:
   1. Enzyme assay, biochemical, or genetic testing results supporting diagnosis; and
   2. Lab results documenting baseline plasma ammonia levels or glutamine levels
B. Continuation of therapy requests: lab results documenting a reduction in plasma ammonia levels from baseline.

III. CRITERIA FOR APPROVAL

Urea Cycle Disorder (UCD) Chronic Management
An authorization of 6 months may be granted for chronic management of urea cycle disorder (UCD) when the following criteria are met:

1. The diagnosis is confirmed by enzymatic, biochemical, or genetic testing.
2. The member has elevated plasma ammonia levels at baseline, evidenced by a lab value of a fasting plasma ammonia level > 0.5 upper limit of normal OR a glutamine level that is > 1,000 μmol/L.
3. Member must have had an inadequate response to and continue to be on a protein restricted diet or amino acid supplementation.
4. Member has documentation of an inadequate response to or inability to tolerate one of the following drugs:
   a. Sodium Phenylbutyrate tablets OR powder
   b. Pheburane
   c. Olpruva (if member weighs 20kg or greater and has a body surface area (BSA) of 1.2 m^2 or greater)

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5. Ravicti is not being used for the management of acute hyperammonemia.
6. The prescribed dose does not exceed 19 grams per day (17.5 ml per day).

IV. CONTINUATION OF THERAPY

If member has not been approved for this drug by Neighborhood in the past, clinician must submit documentation that initial criteria is met. 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.

V. QUANTITY LIMIT

Ravicti 1.1gm/ml: 17.5 ml per day (525ml per 30 days)

VI. REFERENCES

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

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