AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Ravicti® (glycerol phenylbutyrate)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy:** _____

Diagnosis: _____ **ICD Code:** _____

Weight: _____ **Date:** _____

Quantity Limits: 17.5 mL (19 grams) per day

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 12 months

- ❑ Prescriber is a specialist in the management of urea cycle disorders
- ❑ Member is 2 months of age or older and current weight: _____ and height: _____ has been noted by provider
- ❑ Member has a confirmed diagnosis of chronic hyperammonemia due to a urea cycle disorder (UCD) as verified by genetic, enzymatic or biochemical testing **(submit labs confirming diagnosis)**
- ❑ Member does **NOT** have a diagnosis of UCD with N-acetylglutamate synthase (NAGS) deficiency
- ❑ Ravicti will **NOT** be used in treatment of acute hyperammonemia

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- ❑ Member has had a 30-day trial and failure of a sodium phenylbutyrate product (generic Buphenyl®, Pheburane®, Olpruva™) as documented by **ONE** of the following:
  - ❑ Fasting ammonia level > 0.5 times the upper limit of normal while compliantly taking a sodium phenylbutyrate product (generic Buphenyl®, Pheburane®, Olpruva™) **(submit labs for documentation)**
  - ❑ Member has a history of intolerance to a sodium phenylbutyrate product (generic Buphenyl®, Pheburane®, Olpruva™) **(submit chart notes documenting clinically significant medication intolerance and completed Med Watch form)**
- ❑ Member will be maintained on a protein restricted diet while using Ravicti® therapy
- ❑ Members with moderate to severe hepatic impairment (Child-Pugh score B or C) will be initiated on 4.5 mL/m^2/day **(submit current labs including albumin, PT/INR and total bilirubin)**
- ❑ Does the member have some residual enzyme activity? ❑ Yes ❑ No
  - If yes, member must be initiated on 4.5 mL/m^2/day and titrated according to guidelines

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member has been maintained a protein restricted diet while using Ravicti® therapy
- ❑ Member's current weight: _____ and height: _____ must be noted
- ❑ Member has a documented positive clinical response to Ravicti® therapy and fasting ammonia levels have normalized since last approval of Ravicti® **(submit chart notes and labs to support positive)**

Medication being provided by Specialty Pharmacy – Proprium Rx

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*