Amgen By Your Side

is a support program for patients prescribed RAVICTI® (glycerol phenylbutyrate)

Our dedicated team is your patient's partner, committed to providing nonmedical support to help patients as they start and continue on treatment as you prescribe.

Patient Support

Financial Assistance

Insurance Benefits Investigation

Initiate your patient's enrollment in Amgen By Your Side by submitting the Patient Enrollment Form. Patient consent will be required.

OPTIONS AVAILABLE AT:

amgenbyyourside.com/ravicti/hcp

RAVICTI® (glycerol phenylbutyrate) Oral Liquid

Our mission is to connect, coordinate, and champion your patient at important steps along the way:

Connect

Your patient will be connected to one person dedicated to partnering with them throughout their treatment experience

Coordinate

Your patient will receive educational support on insurance, financial assistance options, important appointment-related information, and more

Champion

Your patient's dedicated partner will strive to empower them to be confident self-advocates committed to maintaining their treatment goals

Please see Important Safety Information on page 8 and Full Prescribing Information.

When you are ready to prescribe:

Support access to treatment for your patients

The Amgen By Your Side team is here to assist your patients along the way

Amgen By Your Side offers patient-focused support:

Patient Support

- Provide dedicated, one-on-one support for your patients
- Work directly with individual patients to answer nonmedical, logistical questions and provide support upon enrollment

Insurance Benefits Investigation

- Provide education to you and your staff about product coding and billing
- Educate you and your staff about insurance processes, including specific payor requirements and examples

Financial Assistance

- Educate patients on the results of their benefits investigation and review their insurance coverage
- Help patients understand potential out-of-pocket costs and financial assistance options

Meet the Amgen By Your Side team

Initiate your patient's enrollment in Amgen By Your Side by submitting the Patient Enrollment Form at **amgenbyyourside.com/ravicti/hcp.** Your patient must complete enrollment to access our patient-focused services and resources.

Patient Access Liaison (PAL)

The PAL provides dedicated, one-on-one support for your patient.

- They work directly with individual patients to answer nonmedical, logistical questions and provide support upon enrollment
- Additionally, the PAL educates on navigating insurance processes and accessing treatment
- The PAL has the expertise and tools to support the patient by educating on patient benefits, prior authorization requirements, payor policies, and coding and claim submissions

Case Manager

Case Managers work on behalf of the patient and interact with the doctor's office to obtain accurate insurance information and to inform the office on insurance criteria for the submission of a prior authorization.

In addition, a Case Manager:

- May reach out to the doctor's office after a prescriber initiates enrollment and inquire about missing information on the enrollment form
- Has the expertise and knowledge to educate the doctor's office on payor policies and insurance criteria for access to Amgen products

The team at Amgen By Your Side is available by phone at 1-844-469-4297

Please see Important Safety Information on page 8 and Full Prescribing Information.

Amgen Co-Pay Programs

Eligible patients with commercial insurance may pay as little as $0 out-of-pocket for each prescription fill through the Amgen Commercial Co-Pay Program.*

PALs can speak with patients prescribed RAVICTI about the insurance approval process and help them understand coverage options

*The Amgen Commercial Co-Pay Program may be available to patients who meet the following minimum criteria:

- Patient's prescription cannot be paid in part or in full by any government-funded program including but not limited to: Medicare, Medicare Part D, Medicaid, Medigap, VA, CHAMPUS, Department of Defense (DOD), TRICARE, or any state, patient foundation, or other pharmaceutical program.
- Patient is prescribed a covered Amgen rare disease medication for an indication approved by the Food and Drug Administration; the indication for each product is shown in its prescribing information.
- Patient is a resident of the United States.
- Patient must be commercially insured and have financial responsibility for a portion of the drug and/or infusion cost if applicable.

The assistance offered under this co-pay program is subject to additional terms and conditions, including but not limited to the following:

Terms and Conditions: Offer cannot be combined with any other rebate or coupon, free trial, or similar offer for the specified prescription. Not valid for prescriptions reimbursed in whole or in part by any government-funded program including but not limited to: Medicare, Medicare Part D, Medicaid, Medigap, VA, CHAMPUS, DOD, TRICARE, or any state, patient foundation, or other pharmaceutical program. Offer good only in the United States at participating specialty pharmacies or sites of care. Offer not valid where otherwise prohibited by law, for example by applicable state law prohibiting co-pay cards. Amgen reserves the right to rescind, revoke, or amend offer without notice. The selling, purchasing, trading, or counterfeiting of any co-pay card or benefits is prohibited by law. This co-pay program is not insurance and is not intended to substitute for insurance.

Participating Pharmacies or Healthcare Providers: By using this co-pay program, you acknowledge and confirm that the prescription will not be reimbursed in whole or in part by any government-funded program (such as, without limitation, Medicare, Medicaid, VA, DOD, TRICARE) and the patient and prescription meet the eligibility criteria set forth in the terms and conditions. You are responsible for reporting the receipt of the co-pay program benefits as required by an insurer, payor, or applicable law or regulation.

Patients: By enrolling in this co-pay program, you acknowledge and confirm that you and the prescription meet the eligibility requirements set forth in the terms and conditions, including that the prescription will not be reimbursed in whole or in part by any government-funded program (such as, without limitation, Medicare, Medicaid, VA, DOD, TRICARE). You may not seek any claims to government payors or other payors or insurers for this prescription. You may not seek reimbursement from any health savings, flexible savings, or other healthcare reimbursement account for any amounts received from the co-pay program. You are responsible for reporting the receipt of the co-pay program benefits as required by an insurer, payor, or applicable law or regulation.

Support access to RAVICTI for your patients with Amgen By Your Side

Initiate your patient's enrollment in Amgen By Your Side by submitting the Patient Enrollment Form. Patient consent will be required.

Options available at: **amgenbyyourside.com/ravicti/hcp**

Questions?

Contact the Amgen By Your Side team

Phone:

1-844-469-4297

AMGEN BY your side | RAVICTI® (glycerol phenylbutyrate) Oral Liquid

Please see Indications and Important Safety Information on page 8 and Full Prescribing Information.

INDICATION and IMPORTANT SAFETY INFORMATION

INDICATION

RAVICTI (glycerol phenylbutyrate) Oral Liquid is indicated for use as a nitrogen-binding agent for chronic management of patients with urea cycle disorders (UCDs) who cannot be managed by dietary protein restriction and/or 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).

LIMITATIONS OF USE

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- *Patients with known hypersensitivity to phenylbutyrate:* Reactions include wheezing, dyspnea, coughing, hypotension, flushing, nausea, and rash.

WARNINGS AND PRECAUTIONS

- *Neurotoxicity:* Phenylacetate (PAA), the major metabolite of RAVICTI, may be toxic at levels of 500 micrograms/mL or greater. If symptoms of vomiting, nausea, headache, somnolence, or confusion, are present in the absence of high ammonia or other intercurrent illness which explains these symptoms, consider the potential for PAA neurotoxicity which may need reduction in the RAVICTI dosage.
- *Pancreatic Insufficiency or Intestinal Malabsorption:* Low or absent pancreatic enzymes or intestinal disease resulting in fat malabsorption may result in reduced or absent digestion of RAVICTI and/or absorption of phenylbutyrate and reduced control of plasma ammonia. Monitor ammonia levels closely.

ADVERSE REACTIONS

The most common adverse reactions reported in clinical trials (at least 10% of patients) were:

- *Adult patients:* diarrhea, flatulence, and headache occurred during 4-week treatment (n=45) with RAVICTI; nausea, vomiting, diarrhea, decreased appetite, dizziness, headache, and fatigue occurred during 12-month treatment (n=51) with RAVICTI.
- *Pediatric patients ages 2 to 17 years:* upper abdominal pain, rash, nausea, vomiting, diarrhea, decreased appetite, and headache occurred during 12-month treatment (n=26) with RAVICTI.
- *Pediatric patients ages 2 months to less than 2 years:* neutropenia, vomiting, constipation, diarrhea, pyrexia, hypophagia, cough, nasal congestion, rhinorrhea, rash, and papule occurred during 12-month treatment (n=17) with RAVICTI.
- *Pediatric patients less than 2 months of age:* vomiting, rash, gastroesophageal reflux, increased hepatic enzymes, feeding disorder (decreased appetite, hypophagia), anemia, cough, dehydration, metabolic acidosis, thrombocytosis, thrombocytopenia, neutropenia, lymphocytosis, diarrhea, flatulence, constipation, pyrexia, lethargy, and irritability/agitation occurred during 24-month treatment (n=16) with RAVICTI.

DRUG INTERACTIONS

- Corticosteroids, valproic acid, or haloperidol may increase plasma ammonia level. Monitor ammonia levels closely.
- Probenecid may affect renal excretion of metabolites of RAVICTI, including phenylacetylglutamine (PAGN) and PAA.
- CYP3A4 substrates with narrow therapeutic index (eg, alfentanil, quinidine, cyclosporine): RAVICTI may decrease exposure to the concomitant drug.
- Midazolam: Use of RAVICTI decreased exposure of midazolam with concomitant use.

USE IN SPECIFIC POPULATIONS

- *Pregnancy:* RAVICTI should be used with caution in patients who are pregnant or planning to become pregnant. Based on animal data, RAVICTI may cause fetal harm. Report pregnancies to Horizon at 1-866-479-6742.
- *Lactation:* breastfeeding is not recommended during treatment with RAVICTI. There are no data on the presence of RAVICTI in human milk, the effects on the breastfed infant, nor the effects on milk production.

Please see Full Prescribing Information.

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