Patient Enrollment Form Guide

The Patient Enrollment Form (PEF) must be completely filled out in order to get your patients started on RAVICTI® (glycerol phenylbutyrate) Oral Liquid or BUPHENYL® (sodium phenylbutyrate) Tablets and Powder and initiate their enrollment in Amgen By Your Side, a patient support program. This guide is designed to help you understand the different fields on the form and how to complete the form accurately for submission.

Three easy steps to initiate the patient enrollment process for RAVICTI® (glycerol phenylbutyrate) Oral Liquid or BUPHENYL® (sodium phenylbutyrate) Tablets and Powder:

Fill out all required fields on pages 1 and 2 as indicated by the asterisks, including the prescriber signature and date within the Prescriber section

Obtain the patient consent ("I Consent" check box), patient signature and date within the Patient Consent and Authorization section at the top of page 2, if possible

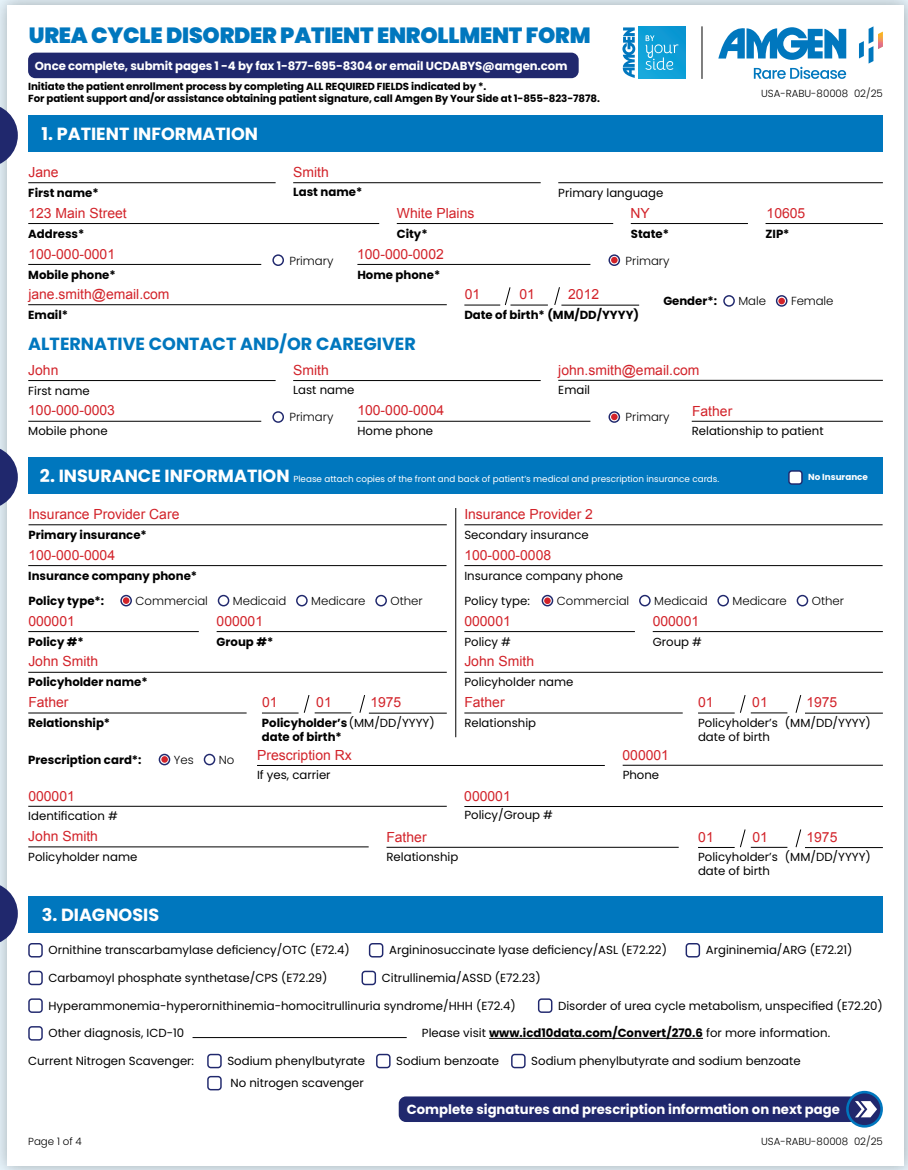
Send both the front and back of the patient's insurance card(s) along with all 4 pages of the PEF

Two ways to submit the Patient Enrollment Form:
- Email: UCDABYS@amgen.com
- Fax: 1-877-695-8304

Please see Important Safety Information for RAVICTI Oral Liquid at the end of this guide, and click here for Full Prescribing Information for RAVICTI.

Please see Important Safety Information for BUPHENYL Tablets and Powder at the end of this guide, and click here for Full Prescribing Information for BUPHENYL.

If you have any questions while completing the form, please contact Amgen By Your Side at 1-855-823-7878.



UREA CYCLE DISORDER PATIENT ENROLLMENT FORM

Once complete, submit pages 1 -4 by fax 1-877-695-8304 or email UCDABYS@amgen.com

Initiate the patient enrollment process by completing ALL REQUIRED FIELDS indicated by *.
For patient support and/or assistance obtaining patient signature, call Amgen By Your Side at 1-855-823-7878.

AMGEN by your side | AMGEN Rare Disease

USA-RABU-80008 02/25

1. PATIENT INFORMATION

Jane — First name*
Smith — Last name*
Primary language
123 Main Street — Address*
White Plains — City*
NY — State*
10605 — ZIP*
100-000-0001 — Mobile phone* ○ Primary
100-000-0002 — Home phone* ◉ Primary
jane.smith@email.com — Email*
01 / 01 / 2012 — Date of birth* (MM/DD/YYYY)
Gender*: ○ Male ◉ Female

ALTERNATIVE CONTACT AND/OR CAREGIVER

John — First name
Smith — Last name
john.smith@email.com — Email
100-000-0003 — Mobile phone ○ Primary
100-000-0004 — Home phone ◉ Primary
Father — Relationship to patient

2. INSURANCE INFORMATION

Please attach copies of the front and back of patient's medical and prescription insurance cards. ☐ No Insurance

Insurance Provider Care — Primary insurance*	Insurance Provider 2 — Secondary insurance
100-000-0004 — Insurance company phone*	100-000-0008 — Insurance company phone
Policy type*: ◉ Commercial ○ Medicaid ○ Medicare ○ Other	Policy type: ◉ Commercial ○ Medicaid ○ Medicare ○ Other
000001 — Policy #*	000001 — Policy #
000001 — Group #*	000001 — Group #
John Smith — Policyholder name*	John Smith — Policyholder name
Father — Relationship*	Father — Relationship
01 / 01 / 1975 — Policyholder's (MM/DD/YYYY) date of birth*	01 / 01 / 1975 — Policyholder's (MM/DD/YYYY) date of birth

Prescription card*: ◉ Yes ○ No
Prescription Rx — If yes, carrier
000001 — Phone
000001 — Identification #
000001 — Policy/Group #
John Smith — Policyholder name
Father — Relationship
01 / 01 / 1975 — Policyholder's (MM/DD/YYYY) date of birth

3. DIAGNOSIS

☐ Ornithine transcarbamylase deficiency/OTC (E72.4) ☐ Argininosuccinate lyase deficiency/ASL (E72.22) ☐ Argininemia/ARG (E72.21)
☐ Carbamoyl phosphate synthetase/CPS (E72.29) ☐ Citrullinemia/ASSD (E72.23)
☐ Hyperammonemia-hyperornithinemia-homocitrullinuria syndrome/HHH (E72.4) ☐ Disorder of urea cycle metabolism, unspecified (E72.20)
☐ Other diagnosis, ICD-10 _____ Please visit www.icd10data.com/Convert/270.6 for more information.
Current Nitrogen Scavenger: ☐ Sodium phenylbutyrate ☐ Sodium benzoate ☐ Sodium phenylbutyrate and sodium benzoate ☐ No nitrogen scavenger

Complete signatures and prescription information on next page

Page 1 of 4

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1 Patient Information

Provide the patient's demographic and contact information; only one patient phone number required, mobile OR home

- Required fields are needed to conduct a benefits investigation, contact the patient for any follow-up, and provide support from Amgen By Your Side
- Alternate contact information is optional
  - It may help to include a caregiver's contact information

2 Insurance Information

Provide the patient's primary insurance information (required to conduct a benefits investigation)

Include secondary insurance information, if applicable, to improve the accuracy of the benefits investigation

If the patient does not have any insurance check the "Patient is uninsured to my knowledge" box

(Continued)

- Please include the front and back of your patient's insurance card(s), if available, along with the completed Patient Enrollment Form
  - If not available, or if the patient is uninsured, you may attach the electronic medical record demographics page as an alternative to the image of the cards

3 Diagnosis

Provide the diagnosis code

- If there is no box, select "Other ICD-10 code" and note the primary diagnosis code
- Select the patient's current nitrogen scavenger or that the patient is not taking one

Disclaimer: The information provided on this form is for demonstration purposes only and does not represent any real person.

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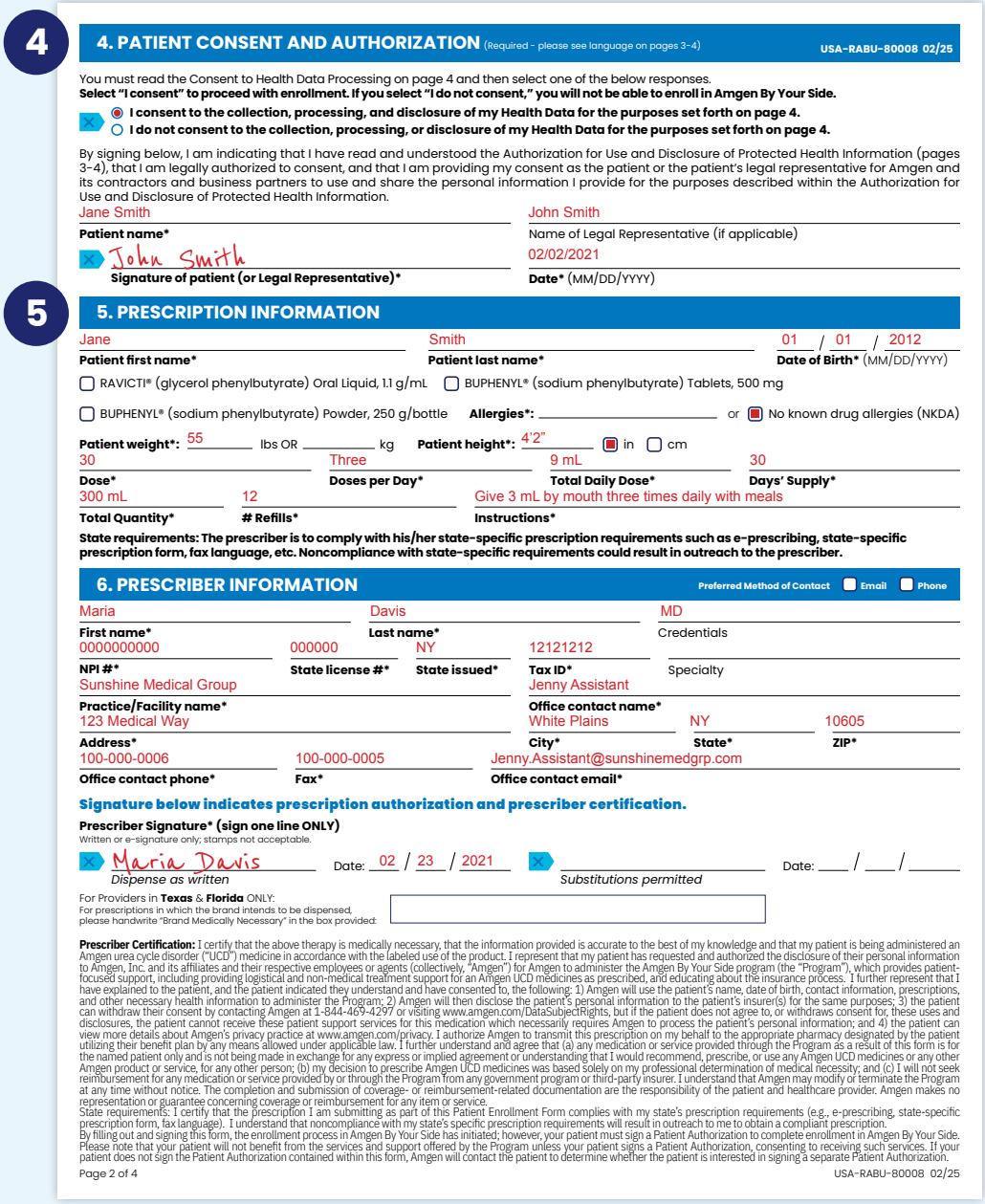
Please see Important Safety Information for BUPHENYL Tablets and Powder at the end of this guide, and click here for Full Prescribing Information for BUPHENYL.



4. PATIENT CONSENT AND AUTHORIZATION (Required - please see language on pages 3-4)

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You must read the Consent to Health Data Processing on page 4 and then select one of the below responses.
Select "I consent" to proceed with enrollment. If you select "I do not consent," you will not be able to enroll in Amgen By Your Side.

- (●) **I consent to the collection, processing, and disclosure of my Health Data for the purposes set forth on page 4.**
- ( ) **I do not consent to the collection, processing, or disclosure of my Health Data for the purposes set forth on page 4.**

By signing below, I am indicating that I have read and understood the Authorization for Use and Disclosure of Protected Health Information (pages 3-4), that I am legally authorized to consent, and that I am providing my consent as the patient or the patient's legal representative for Amgen and its contractors and business partners to use and share the personal information I provide for the purposes described within the Authorization for Use and Disclosure of Protected Health Information.

Jane Smith — **Patient name***

John Smith — Name of Legal Representative (if applicable)

John Smith — **Signature of patient (or Legal Representative)***

02/02/2021 — **Date*** (MM/DD/YYYY)

5. PRESCRIPTION INFORMATION

Jane — **Patient first name***

Smith — **Patient last name***

01 / 01 / 2012 — **Date of Birth*** (MM/DD/YYYY)

☐ RAVICTI® (glycerol phenylbutyrate) Oral Liquid, 1.1 g/mL ☐ BUPHENYL® (sodium phenylbutyrate) Tablets, 500 mg

☐ BUPHENYL® (sodium phenylbutyrate) Powder, 250 g/bottle **Allergies*:** _____ or ■ No known drug allergies (NKDA)

Patient weight*: 55 lbs OR _____ kg **Patient height*:** 4'2" ■ in ☐ cm

30	Three	9 mL	30
Dose*	**Doses per Day***	**Total Daily Dose***	**Days' Supply***

300 mL	12	Give 3 mL by mouth three times daily with meals
Total Quantity*	**# Refills***	**Instructions***

State requirements: The prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Noncompliance with state-specific requirements could result in outreach to the prescriber.

6. PRESCRIBER INFORMATION

Preferred Method of Contact ☐ Email ☐ Phone

Maria	Davis	MD
First name*	**Last name***	Credentials

0000000000	000000	NY	12121212	
NPI #*	**State license #***	**State issued***	**Tax ID***	Specialty

Sunshine Medical Group — **Practice/Facility name***

Jenny Assistant — **Office contact name***

123 Medical Way — **Address***

White Plains	NY	10605
City*	**State***	**ZIP***

100-000-0006	100-000-0005	Jenny.Assistant@sunshinemedgrp.com
Office contact phone*	**Fax***	**Office contact email***

Signature below indicates prescription authorization and prescriber certification.

Prescriber Signature* (sign one line ONLY)
Written or e-signature only; stamps not acceptable.

Maria Davis — *Dispense as written* Date: 02 / 23 / 2021

_____ — *Substitutions permitted* Date: ___ / ___ / ____

For Providers in **Texas** & **Florida** ONLY:
For prescriptions in which the brand intends to be dispensed, please handwrite "Brand Medically Necessary" in the box provided:

Prescriber Certification: I certify that the above therapy is medically necessary, that the information provided is accurate to the best of my knowledge and that my patient is being administered an Amgen urea cycle disorder ("UCD") medicine in accordance with the labeled use of the product. I represent that my patient has requested and authorized the disclosure of their personal information to Amgen, Inc. and its affiliates and their respective employees or agents (collectively, "Amgen") for Amgen to administer the Amgen By Your Side program (the "Program"), which provides patient-focused support, including providing logistical and non-medical treatment support for an Amgen UCD medicines as prescribed, and educating about the insurance process. I further represent that I have explained to the patient, and the patient indicated they understand and have consented to, the following: 1) Amgen will use the patient's name, date of birth, contact information, prescriptions, and other necessary health information to administer the Program; 2) Amgen will then disclose the patient's personal information to the patient's insurer(s) for the same purposes; 3) the patient can withdraw their consent by contacting Amgen at 1-844-469-4297 or visiting www.amgen.com/DataSubjectRights, but if the patient does not agree to, or withdraws consent for, these uses and disclosures, the patient cannot receive these patient support services for this medication which necessarily requires Amgen to process the patient's personal information; and 4) the patient can view more details about Amgen's privacy practice at www.amgen.com/privacy. I authorize Amgen to transmit this prescription on my behalf to the appropriate pharmacy designated by the patient utilizing their benefit plan by any means allowed under applicable law. I further understand and agree that (a) any medication or service provided through the Program as a result of this form is for the named patient only and is not being made in exchange for any express or implied agreement or understanding that I would recommend, prescribe, or use any Amgen UCD medicines or any other Amgen product or service, for any other person; (b) my decision to prescribe Amgen UCD medicines was based solely on my professional determination of medical necessity; and (c) I will not seek reimbursement for any medication or service provided by or through the Program from any government program or third-party insurer. I understand that Amgen may modify or terminate the Program at any time without notice. The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and healthcare provider. Amgen makes no representation or guarantee concerning coverage or reimbursement for any item or service.
State requirements: I certify that the prescription I am submitting as part of this Patient Enrollment Form complies with my state's prescription requirements (e.g., e-prescribing, state-specific prescription form, fax language). I understand that noncompliance with my state's specific prescription requirements will result in outreach to me to obtain a compliant prescription.
By filling out and signing this form, the enrollment process in Amgen By Your Side has initiated; however, your patient must sign a Patient Authorization to complete enrollment in Amgen By Your Side. Please note that your patient will not benefit from the services and support offered by the Program unless your patient signs a Patient Authorization, consenting to receiving such services. If your patient does not sign the Patient Authorization contained within this form, Amgen will contact the patient to determine whether the patient is interested in signing a separate Patient Authorization.

4 Patient Consent and Authorization

- Patient must sign and date form
- Patient must check "I consent" circle in order to be enrolled in Amgen By Your Side
- If the patient can't sign the form at your office, Amgen By Your Side can follow up to obtain consent

5 Prescription Information

All prescription fields must be fully completed. Incomplete information may result in delays at specialty pharmacies and additional outreach for prescription clarification.

6 Prescriber Information

- Provide the prescriber's name, contact information, NPI, tax ID, and state license numbers, which are required for processing
- Prescriber signature is required for processing the Patient Enrollment Form
  - Must be a written or e-signature, stamps are not accepted

**Pages 3-4 of the PEF include the patient authorization and consent language.
Once the PEF is submitted, you can provide these 2 pages to the patient for their reference.**

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Connecting Patients with their Amgen By Your Side PAL

The Patient Access Liaison (PAL) is a dedicated support partner who helps investigate, explain, and educate on the steps in your patient's treatment experience. They are your patient's point of contact and champion while your patient is accomplishing their treatment goals.

☐ Make sure the patient is aware their PAL will be calling them in the next few days to provide information on next steps and getting started on Amgen urea cycle disorder (UCD) medicines

☐ Have the patient save their PAL's contact in their phone
- **It is important that a patient answers the PAL's call**

PAL Name: _____ **Phone Number:** _____

Please ensure that all four pages of the enrollment forms are submitted by fax to 1-877-695-8304 or emailed to UCDABYS@amgen.com. Incomplete forms may delay enrollment.

INDICATION and IMPORTANT SAFETY INFORMATION FOR BUPHENYL (SODIUM PHENYLBUTYRATE) TABLETS AND POWDER

INDICATION

BUPHENYL® (sodium phenylbutyrate) Tablets for oral administration and BUPHENYL® (sodium phenylbutyrate) Powder for oral, nasogastric, or gastrostomy tube administration are indicated as adjunctive therapy in the chronic management of patients with urea cycle disorders (UCDs) involving deficiencies of carbamoyl phosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS).

BUPHENYL is indicated in all patients with neonatal-onset deficiency (complete enzymatic deficiency, presenting within the first 28 days of life). It is also indicated in patients with late-onset disease (partial enzymatic deficiency, presenting after the first month of life) who have a history of hyperammonemic encephalopathy.

BUPHENYL must be used with dietary protein restriction and, in some cases, essential amino acid supplementation.

Any episode of acute hyperammonemia should be treated as a life-threatening emergency.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- *Acute hyperammonemia*: BUPHENYL should not be used to manage acute hyperammonemia, which is a medical emergency.

WARNINGS AND PRECAUTIONS

BUPHENYL should not be administered to patients with known hypersensitivity to sodium phenylbutyrate or any component of this preparation.
- Use caution with administering BUPHENYL to patients with:
  - Congestive heart failure or severe renal insufficiency, and in clinical states in which there is sodium retention with edema.
  - Hepatic or renal insufficiency or inborn errors of beta oxidation.
- Probenecid may affect renal excretion of the conjugated product of BUPHENYL as well as its metabolite.
- Use of corticosteroids may cause the breakdown of body protein and increase plasma ammonia levels.
- There have been published reports of hyperammonemia being induced by haloperidol and by valproic acid.

ADVERSE REACTIONS

- The most common adverse reactions (≥3%) reported in BUPHENYL clinical trials were decreased appetite, body odor, bad taste or taste aversion.
- In female patients, amenorrhea/menstrual dysfunction (irregular menstrual cycles) occurred in 23% of the menstruating patients.
- Neurotoxicity was reported in cancer patients receiving intravenous phenylacetate. Manifestations were predominately somnolence, fatigue, and lightheadedness; with less frequent headache, dysgeusia, hypoacusis, disorientation, impaired memory, and exacerbation of a pre-existing neuropathy.
- Laboratory adverse events occurring in >2% of UCD patients by body system were:
  - *Metabolic*: acidosis, alkalosis, hyperchloremia, and hypophosphatemia
  - *Nutritional*: hypoalbuminemia and decreased total protein
  - *Hepatic*: increased alkaline phosphatase and increased liver transaminases
  - *Hematologic*: anemia, leukopenia, leukocytosis, and thrombocytopenia

USE IN SPECIFIC POPULATIONS

- *Pregnancy*: BUPHENYL should be used with caution in patients who are pregnant or planning to become pregnant. Animal reproduction studies have not been conducted with BUPHENYL. It is not known whether BUPHENYL can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.
- *Lactation*: breastfeeding is not recommended during treatment with BUPHENYL. There are no data on the presence of BUPHENYL in human milk.

Please see Full Prescribing Information.

INDICATION and IMPORTANT SAFETY INFORMATION FOR RAVICTI (GLYCEROL PHENYLBUTYRATE) ORAL LIQUID

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 Amgen 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.

AMGEN Rare Disease