

RAVICTI[®] (glycerol phenylbutyrate) Oral Liquid Access Journey

A resource to educate healthcare providers about patient access and coverage

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.

Please see additional Important Safety Information on pages 12-13 and see accompanying [Full Prescribing Information](#) or visit RAVICTIhcp.com.





Road Map



Amgen By Your Side Overview



Initiate Patient Enrollment



Conduct a Benefits Investigation



Submit a Prior Authorization



Submit an Appeal



Best Practices



Indication and Important Safety Information

RAVICTI Patient Access Road Map

This resource can help you identify the steps in the access process as well as available resources.

You can navigate through the road map by clicking on areas of the map or by using the navigation bar above. In each section, you will find more detailed information and resources available for that step of the process.

Patient enrollment in AMGEN BY YOUR SIDE



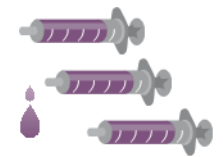
Conduct a BENEFITS INVESTIGATION (BI)



Submit a PRIOR AUTHORIZATION (PA)



Coverage APPROVAL



RAVICTI Oral Liquid ordered and dispensed by the specialty pharmacy



Amgen By Your Side is a support program for patients prescribed RAVICTI. Our dedicated team is your patient's partner, committed to providing nonmedical support to help patients as they start and continue on treatment as prescribed.

Call **1-844-469-4297**

Monday–Friday, 9 AM–8 PM ET

www.AmgenByYourSide.com



Coverage Denial



Submit an Appeal*

*Submitting an appeal does not guarantee approval, and this process may need to be repeated.

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Amgen Offers Patients a Range of Support Throughout Their Access and Treatment Journey

Coverage policies may vary, and the team at **Amgen By Your Side** can educate you and your staff about insurance processes, including specific payor requirements and examples.



Amgen By Your Side

Amgen By Your Side is a support program for patients prescribed RAVICTI. After your patient has enrolled, they will be paired with a dedicated support partner called a [\[Patient Access Liaison \(PAL\)\]](#).



[\[PAL\]](#)

The [\[PAL\]](#) can be a partner, providing nonmedical education to help your patient navigate their unique treatment experience—including information on insurance, financial assistance options, important appointment-related information, and other patient support services.



Amgen [\[Case Manager\]](#)

The [\[Case Manager\]](#) can help healthcare providers understand their patients' benefits and unique access solutions. A [\[Case Manager\]](#) assigned to your patients may also be in touch with your office to make sure important insurance information is properly shared.

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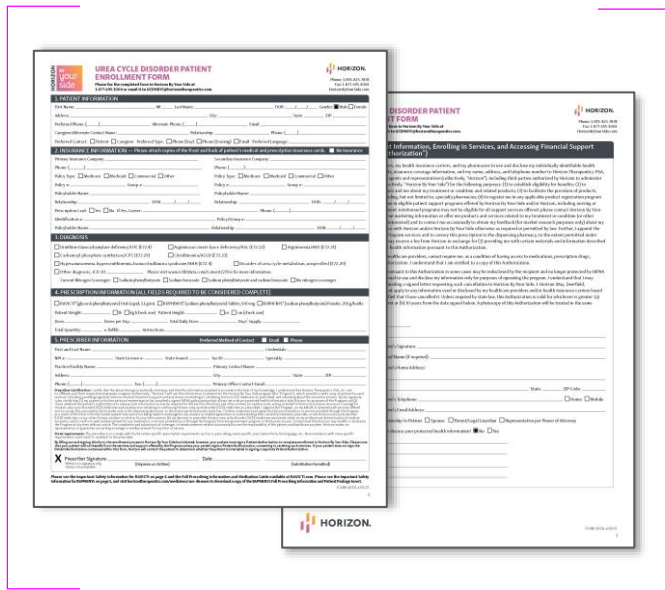
Best Practices



Indication and Important Safety Information

Initiate Patient Enrollment

Many treatments require initial action from the healthcare provider and office staff for patients to get access to RAVICTI. The **Amgen By Your Side** Team is led by a **[Patient Access Liaison (PAL)]**. The **[PAL]** is a dedicated support partner who helps investigate, explain, and educate on the steps in the treatment experience. They are your patient's point of contact and champion while your patient is accomplishing their treatment goals.



The Patient Enrollment Form (PEF) is the first step for your patients to receive support from the team at Amgen By Your Side, including:

- **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
- **Educate** you and your staff about insurance processes, including specific payor requirements and examples
- **Provide** education to you and your staff about product coding
- **Share** additional resources that may be helpful as your patient gets started



DOWNLOAD the PEF to initiate patient enrollment in Amgen By Your Side.



DOWNLOAD the Annotated PEF, a resource that provides details about the PEF.

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Conduct a Benefits Investigation (BI)

Coverage criteria will vary among medical plans and a BI will identify requirements specific to RAVICTI. A [\[Case Manager\]](#) can help educate you and your patient about the insurance process and accessing treatment.

A BI may help answer questions about:

RAVICTI coverage

- Is RAVICTI covered under the medical benefit or pharmacy benefit?

PA

- Will a PA be required for treatment with RAVICTI?
- If a PA is not required, is predetermination available?
- What is the process for obtaining a PA or predetermination?
- What information will be required and how long will the process take?
- How long will the PA remain valid?

Benefits coordination

- Does the patient have any other supplemental insurance benefits that would require coordination? Which benefit is primary? Which is secondary?



[\[DOWNLOAD\]](#) the RAVICTI PA Checklist to help your office organize the information that may be needed for a PA.

Patient financial responsibility and out-of-pocket (OOP) costs

- What is the annual deductible amount the patient must meet?
 - Has this amount been met?
 - How much is left?
- What is the patient's co-payment or co-insurance for RAVICTI?
- Is there a maximum OOP amount that the patient must meet?
 - Has this amount been met?
 - How much is left?

Prescription information

- Is RAVICTI medically appropriate?
- Is RAVICTI being prescribed in accordance with generally accepted standards of medical practice?

PA, prior authorization.

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Conduct a Benefits Investigation (BI) (cont'd)

Coding and claims submission

A BI can help answer questions such as:

- What are the specific coding and claims submission requirements for prescribing RAVICTI in this patient’s plan?
- What type of documentation is required?

Reminder: Requirements for coverage will vary among health plans and a BI will identify requirements specific to RAVICTI, as well as what insurance your patient has.

RAVICTI ICD-10-CM Code*	
Code	Description
E72.20	Disorder of urea cycle metabolism, unspecified
E72.4	OTCD
E72.22	ASLD
E72.21	ARGD
E72.29	CPS1D
E72.23	ASSD
E72.4	HHH

RAVICTI NDC Codes	
Code	Description
75987-050-06	One 25-mL bottle per carton
75987-050-07	Four 25-mL bottles per carton

Once the team at Amgen By Your Side completes the BI, you will receive a Summary of Benefits notification generally within 1 to 2 business days of insurance verification.

*This may not be the only applicable code for reimbursement, nor does using this code guarantee coverage. ARGD, arginase deficiency; ASLD, argininosuccinate lyase deficiency; ASSD, argininosuccinate synthetase deficiency; CPS1D, carbamoyl phosphate synthetase 1 deficiency; HHH, hyperornithinemia-hyperammonemia-homocitrullinuria; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; NDC, National Drug Code; OTCD, ornithine transcarbamylase deficiency.

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Submit a Prior Authorization (PA)

The PA process allows the health plan to review the reason for treatment with RAVICTI and to determine if it is medically necessary. Clinical documentation requirements will vary among health plans.

Common criteria a health plan policy may require for a PA:

Diagnosis information

- Diagnosis/ICD-10-CM codes
- Diagnosis confirmed through enzymatic, biochemical, or genetic testing
- Chronic hyperammonemia
- Ammonia levels
- Documentation of functional impairment

Treatment history

- Provide documentation showing that the patient is following a protein-restricted diet or amino acid supplementation
- Note if the patient has experienced inadequate response to treatment or intolerance to use of other nitrogen scavenger medicines; include dosage and duration
- For patients already on RAVICTI, provide documentation showing clinical improvement
- Note any consultations with a specialist (eg, metabolic geneticist, metabolic dietitian, genetics counselor)

Including a letter of medical necessity with a PA is important and may help avoid delays.

Your office may need to connect with the referring physician to gather the clinical documentation required to complete the PA. The dedicated [Case Manager] has the local expertise to provide education about PA, medical exception, or appeal processes.

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

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Submit a Prior Authorization (PA) (cont'd)

The PA process allows the health plan to review the reason for the requested therapy and to determine medical appropriateness. Clinical documentation requirements will vary among health plans. When submitting a PA for RAVICTI, be sure to:

- ✓ **Submit the PA directly to the health plan or by using an electronic PA system such as CoverMyMeds®**
- ✓ **Thoroughly complete every section of the PA form and review the medical policy carefully, as each health plan may have unique requirements**
- ✓ **Provide supporting documentation, including but not limited to:**
 - Medical records
 - Diagnosis confirmed by one of the following methods: enzymatic, biochemical, or genetic testing
 - Chart notes
 - Publications and references
 - A letter of medical necessity
- ✓ **Inquire about how long the process will take once necessary documents have been submitted**



[DOWNLOAD] the PA Checklist for reminders and recommendations for submitting a PA.



[DOWNLOAD] the Letter of Medical Necessity Template and print it out on your office letterhead.

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Submit an Appeal

An appeal letter may be needed if a PA for RAVICTI is denied. When writing an appeal letter, ensure that you address the specific details of the denial reason(s), refer to the letter of denial for specific language regarding the reason for denial, and address any concerns that are patient-specific.

Supplemental documentation may include:

- Relevant clinical notes for your patient
- Recent test results
- Supporting scientific publications/journal articles
- A summary of your recommendation at the end of the letter
- A letter of medical necessity

Make sure you match the exact language from the denial letter. It is imperative to address the specifics of the denial in the appeal letter. Before you submit your appeal, make sure to:

- Check for any incomplete or missing information, as this is a common reason for denial
- Schedule a peer-to-peer meeting with the health plan
- Contact a [\[Case Manager\]](#) to learn about additional resources and next steps in the process

If a letter of medical necessity was not submitted with the PA, consider including it with the appeal letter.

Contact the health plan to learn about the appeal review timeline. Once you have submitted the letter, along with any supporting documentation, most health plans will review and decide on coverage within approximately:



72 HOURS
for urgent care



30 DAYS
for nonurgent care



60 DAYS
for services already provided

To initiate an expedited appeal, contact your patient's health plan to confirm its instructions for expedited requests.



DOWNLOAD the Appeal Letter Template to help your office draft an appeal letter.



DOWNLOAD the Payor Appeal Letter Checklist and Tips to help you through the appeal process.

PA, prior authorization.

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Best Practices to Maintain Throughout the Access Journey



DOCUMENT

Keep a record of policy requirements, which may vary considerably among health plans.



IDENTIFY

Ensuring smooth transactions among the provider, health plan, and patient starts with identifying each health plan's policy early on.



KNOW

Health plan policies provide clarity for patients on their coverage and OOP expenses.



CONTACT

Our [\[Case Managers\]](#) are ready to assist you with your questions.



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

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OOP, out-of-pocket.

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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.

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IMPORTANT SAFETY INFORMATION (cont'd)

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](#) or visit RAVICTIhcp.com.



RAVICTI[®]
(glycerol phenylbutyrate) Oral Liquid



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