

Tips for Filing an Appeal of Treatment Denial

A written appeal letter should follow the requirements of the patient's health plan, including the use of plan-specific coverage authorization forms. Contact the specific health plan for information that is pertinent to your appeal. Once you have this information, it may be helpful to follow the tips and checklist in this document as you write the appeal.

The focus of this document is to assist you in the preparation of a comprehensive appeal that may meet the requirements of a specific health plan. Use of the information in this document does not guarantee that the health plan will reverse its denial, and it is not intended to be a substitute for, or an influence on, your independent medical judgment.

Use of this document is for HCP office staff only.

Why Was the Request Denied?

Determine (in writing) why your prior authorization request has been denied by the patient's health plan. This information may be outlined in the explanation of benefits (EOB) letter that can be obtained from the health plan. Check the health plan's online portal for more information.

Understand the Appeal Guidelines

Appeal periods vary, so it is important to find out the deadline for submitting an appeal. Also determine the number of appeals because some plans allow only one. Confirm routine information, such as the current mailing address/fax number for the appeal. Consider setting up a consultation with the health plan's representative to discuss.

Phone the Health Plan's Review Department

If the denial letter includes a phone number for the review department, the prescribing physician should call to learn of any details regarding why the request was denied. If the reviewer approves treatment during the call, then confirm the appeal process is complete and documented. If this does not happen, then continue with the process.

Draft the Appeal Letter

Write the appeal letter and include all of the supporting documentation that you may need. You may also need to schedule a peer-to-peer consultation in order to obtain required details or documentation.

Please see Important Safety Information on page 3 and accompanying [Prescribing Information](#), including Instructions for Use at www.carbaglu.com.

Submit Final Appeal Letter and Supporting Documentation

The appeal should include all relevant medical documentation. This documentation may include clinical notes and test results, as well as any other relevant information regarding the patient's current condition. Additional documents may also be required depending on the specific payor.

Determine the Timeline

Confirm the appeal review timeline with the health plan. Typically, you will hear from the health plan within 30 to 60 days of receipt of the appeal package. Follow up as needed.

Keep Comprehensive Records

Keep copies of all documents and notes associated with the appeal. Likewise, any communication occurring during and after the appeal is submitted should be carefully documented, including dates, the person with whom you spoke, and any details pertinent to the appeal.

Documents for Filing an Appeal

Each appeal may require different information based on the health plan's requirements. Review each denial and the plan's requirements to determine what to include in a patient's appeal package.

Below is a list of records that are commonly included in an appeal package.

Frequently Needed Documents for an Appeal Package

- Letter of appeal
- Letter of medical necessity
- Patient authorization and notice of release of information
- Copy of the patient's medical plan card and/or prescription card (front and back)
- Denial information, including the patient's denial letter and/or explanation of benefits
- Supporting documentation:
 - CARBAGLU Prescribing Information
 - CARBAGLU clinical studies
 - Clinical documentation such as, but not limited to:
 - Plasma ammonia levels
 - Genetic test confirming NAGS deficiency, propionic acidemia, or methylmalonic acidemia
 - Treatment history, including therapeutics, dosage, and duration
 - Any relevant clinical/chart notes, such as renal impairment comorbidity

Please see **Important Safety Information on page 3** and accompanying **Prescribing Information**, including **Instructions for Use** at www.carbaglu.com.

Carbaglu[®]
(carglumic acid) tablets for oral suspension
200mg

Indications and Usage

CARBAGLU® (carglumic acid) is a carbamoyl phosphate synthetase 1 (CPS 1) activator indicated in adult and pediatric patients as:

Acute and Chronic Hyperammonemia due to N-acetylglutamate Synthase (NAGS) Deficiency:

- Adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency.
- Maintenance therapy for the treatment of chronic hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency.

Acute Hyperammonemia due to Propionic Acidemia (PA) or Methylmalonic Acidemia (MMA)

- Adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA).

Important Safety Information

- **Contraindications:** none.
- **NAGS deficiency: the most common adverse reactions** ($\geq 13\%$) are vomiting, abdominal pain, pyrexia, tonsillitis, anemia, diarrhea, ear infection, infections, nasopharyngitis, hemoglobin decreased, and headache.
- **PA and MMA: the most common adverse reactions** ($\geq 5\%$) are neutropenia, anemia, vomiting, electrolyte imbalance, decreased appetite, hypoglycemia, lethargy/stupor, encephalopathy and pancreatitis/lipase increased.
- **To report SUSPECTED ADVERSE REACTIONS, contact Recordati Rare Diseases Inc. at 1-888-575-8344, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**
- **Use in Special Population(s):** if CARBAGLU is administered during pregnancy to women with NAGS deficiency, health care providers should report CARBAGLU exposure to the pregnancy pharmacovigilance program by calling 1-888-575-8344.
- **Dosing and Administration:** the recommended dosage of CARBAGLU in patients with moderate or severe renal impairment must be adjusted based upon the estimated glomerular filtration rate (eGFR). See Prescribing Information for details.
- CARBAGLU® (carglumic acid) is available as 200 mg tablets for oral suspension.

Please see accompanying [Prescribing Information](#), including Instructions for Use at www.carbaglu.com.