

Carbaglu®

(carglumic acid) tablets for oral suspension

200mg

Appeals Resource for Healthcare Providers

A sample letter to help ensure that your communications with health plans are as complete as possible

Indications and Usage

CARBAGLU® (carglumic acid) tablets for oral suspension 200mg is a carbamoyl phosphate synthetase 1 (CPS1) activator indicated in pediatric and adult patients as:

- 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.
- 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: 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: 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.**
- 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.

This sample letter and related information are provided for informational purposes only. It is the responsibility of the HCP and/or their office staff, as appropriate, to determine the correct diagnosis, treatment protocol, and content of all such letters and related forms for each individual patient. Recordati Rare Diseases (RRD) does not guarantee coverage or reimbursement for the product. There is no requirement that any patient or healthcare provider use any RRD product in exchange for this information, and this template is not meant to substitute for a prescriber's independent medical decision-making.

[Please see Full Prescribing Information, including Instructions for Use.](#)

Sample Letter of Medical Necessity

(ON OFFICE LETTERHEAD INCLUDING PROVIDER NAME AND ADDRESS)

(Date)

(Payer Name)

(Payer Address)

Patient Name: (Patient Name)

Patient Date of Birth: (Patient DOB)

Policy Number: (Policy Number)

Group Number: (Group Number)

Case Number: (Case Number)

Subject: Letter of Appeal regarding CARBAGLU (carglumic acid) tablets for oral suspension 200mg

To Whom It May Concern:

I am writing to request an APPEAL of the decision to deny CARBAGLU coverage for my patient (**patient name**). (**Patient name**) has been diagnosed with (**diagnosis**) and requires treatment for (**reason for treatment**) associated with this condition. My patient has taken CARBAGLU for (**X years/months**), and it is important this patient continues to receive CARBAGLU as I prescribed.

Our office received a denial for CARBAGLU on (**date**). In that denial, CARBAGLU was denied due to the following reason(s):

- 1.
- 2.
- 3.

I disagree with this decision. In my clinical judgement, treatment with CARBAGLU is medically necessary due to the following reason(s) (**answer each reason why CARBAGLU was denied. Include relevant medical information to support your diagnosis and reason for treatment with CARBAGLU**):

- 1.
- 2.
- 3.

I would appreciate your reconsideration of this denial and ask that you reverse your decision and approve CARBAGLU for (**patient name**).

My intended dose of CARBAGLU for this patient is (**dose**).

If you have any questions or wish to conduct a Peer-to-Peer discussion, feel free to contact me at (**phone number**).

Thank you for your time and consideration.

(**First and Last name, MD**)

Encl: Medical Records