

SENTARA COMMUNITY PLAN (MEDICAID)

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; fax to 1-800-750-9692. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. If information provided is not complete, correct, or legible, authorization may be delayed.

Drug Requested: carglumic acid (Carbaglu®)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight: _____ Date: _____

Recommended Dosage:

- NAGS deficiency, acute hyperammonemia: 100 to 250 mg/kg/day given in 2 to 4 divided doses
- NAGS deficiency, chronic hyperammonemia: 10 to 100 mg/kg/day given in 2 to 4 divided doses
- Propionic acidemia or methylmalonic acidemia, acute hyperammonemia: Oral: 3.3g/m²/day in 2 divided doses (12 hours apart) and for a maximum of 7 days

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

(Continued on next page)

N-acetylglutamate synthase (NAGS) deficiency

Initial Authorization: 6 months

- Provider is or has consulted with a specialist in medical genetics or other specialist in treatment of urea cycle disorders
- Member has diagnosis of NAGS deficiency as confirmed by genetic testing (**submit results**)
- Member is experiencing hyperammonemia despite compliance with standard therapy (**submit current plasma ammonia lab test results and chart notes documenting therapies tried**)
- For treatment of acute hyperammonemia, carglumic acid will be used in conjunction with standard therapy (i.e. hemodialysis, intravenous sodium benzoate and phenylacetate, protein restriction)
- Prescribed dose will not exceed 250 mg/kg per day initially, followed by a maintenance dose of 100 mg/kg per day
- For approval of brand name Carbaglu: Member has had trial and intolerable life-endangering adverse event with generic carglumic acid tablets (**must submit completed MedWatch form and chart notes to document adverse event**)

N-acetylglutamate synthase (NAGS) deficiency

Reauthorization: 12 months.

- All initial authorization criteria continues to be met
- Member's plasma ammonia levels have been sustained at or below normal limits for age (**submit current lab test results**)
- Member is **NOT** experiencing any symptoms of unacceptable toxicity associated with carglumic acid
- For approval of brand name Carbaglu: Member has had trial and intolerable life-endangering adverse event with generic carglumic acid tablets (**must submit completed MedWatch form and chart notes to document adverse event**)

Propionic Acidemia (PA) or Methylmalonic Acidemia (MMA) with acute hyperammonemia

Authorization Criteria: 7 day length of authorization. Coverage cannot be renewed.

- Provider is or has consulted with a specialist in medical genetics or other specialist in treatment of urea cycle disorders
- Member has diagnosis of propionic acidemia or methylmalonic acidemia as confirmed by genetic testing (**submit results**)
- Member's plasma ammonia level is ≥ 70 $\mu\text{mol/L}$ despite standard of care treatment, such as intravenous hydration and nutritional support (**submit current plasma ammonia lab test results and chart notes documenting therapies tried**)

Carglumic Acid (Pharmacy) (Medicaid)
(Continued from previous page)

- ❑ Medication will be used in conjunction with other ammonia-lowering therapies (i.e. intravenous glucose, insulin, L-carnitine, protein restriction, hemodialysis)
- ❑ Medication will only be used until the patient's ammonia level is $< 50 \mu\text{mol/L}$ and for a maximum duration of 7 days

For approval of brand name Carbaglu: Member has had trial and intolerable life-endangering adverse event with generic carglumic acid tablets (**must submit completed MedWatch form and chart notes to document adverse event**)

Medication being provided by Specialty Pharmacy - PropriumRx

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****