

Carbaglu (Carglumic Acid) Criteria

Revised: 04/01/2026

CARBAGLU (CARGLUMIC ACID)

Length of Authorization: NAGS deficiency: 1 year
PA or MMA: 1 month

CHILDREN – CRITERIA TO APPROVE

- The patient is 0 to 17 years of age
- **One** of the following diagnoses:
 - Adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency; **OR**
 - Maintenance therapy for the treatment of chronic hyperammonemia due to NAGS deficiency; **OR**
 - Adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA)
- The medical charts document elevated ammonia level of ≥ 100 micromol/L (within the previous 3 months)
- The prescriber specialty is nephrology or metabolic disorders, or the prescriber has consulted with a specialist.

ADULTS – CRITERIA TO APPROVE

- The patient is 18 years of age or older
- **One** of the following diagnoses:
 - Adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency; **OR**
 - Maintenance therapy for the treatment of chronic hyperammonemia due to NAGS deficiency; **OR**
 - Adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA)
- The medical charts document elevated ammonia level of ≥ 60 micromol/L (within the previous 3 months)
- The prescriber specialty is nephrology or metabolic disorders, or the prescriber has consulted with a specialist.

RENEWAL CRITERIA

All the following:

- The patient met initial review requirements; **AND**
- The patient has an overall clinical improvement in response to therapy including documentation within the previous 6 months of normal (children: 40–80 micromol/L; adults: < 30 micromol/L) or improved ammonia level; **AND**
- The patient has not experienced any treatment-restricting adverse events.
- **Note:** Carbaglu for methylmalonic acidemia (MMA) or propionic acidemia (PA) should always be reviewed under Initial Review

REVISION HISTORY

Date	Issues/Updates
04/01/2026	• Initial creation