Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	February 3, 2011 April 13, 2012, September 17, 2021

CARBAGLU® (carglumic acid)

LENGTH OF AUTHORIZATION: Up to 6 months

INITIAL REVIEW CRITERIA:

- Patient must have a confirmed diagnosis for one of the following (per submitted medical records):
  - 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).
- Patient must have official lab results dated within the past 3 months, indicating an elevated ammonia level.

CONTINUATION OF THERAPY:

- Patient met initial approval criteria.
- Patient must have official lab results dated within the past 6 months, indicating a normal or improved ammonia level.

DOSING and ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
  - Available as 200 mg tablets.