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

CARBAGLU® (carglumic acid)

LENGTH OF AUTHORIZATION: UP TO SIX MONTHS

REVIEW CRITERIA:

- Must have a confirmed diagnosis or history of hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (per submitted medical records).
    - INITIATION OF THERAPY: Copy of official lab results, dated within the past 3 months, must be submitted indicating an elevated ammonia level.
    - CONTINUATION OF THERAPY: Copy of official lab results, dated within the past 6 months, must be submitted indicating a normal or improved ammonia level.

DOSING:

- *Adults, Adolescents, Children, Infants, and Neonates:* Initially, 100 mg/kg/day to 250 mg/kg/day PO divided into 2 to 4 doses per day.
- For adults, round the dose to the nearest 100 mg. Titrate the dose based on individual patient plasma ammonia concentrations and clinical symptoms. Titrate the maintenance dose to target a normal plasma ammonia concentration for age.
- Maintenance doses were usually less than 100 mg/kg/day among 22 patients in a retrospective case series.
- Doses to be given immediately before meals or feedings.
- Each 200 mg tablet should be dispersed in a minimum of 2.5 ml of water to yield a concentration of 80mg/ml and taken immediately.
- Carbaglu® may be administered orally or via a nasogastric tube.