Office of Pharmacy Services
Prior Authorization Criteria

Carbaglu (Carglumic Acid)

Requests for Carbaglu Tablets will be approved if the following prior authorization criteria are met:

1. **Adjunctive therapy for the treatment of acute hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS)**

   or

2. **Maintenance therapy for the treatment of chronic hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS)**

   and

3. **Patient has a diagnosis of hyperammonemia due to the defiency of the hepatic enzyme-N-acetylglutamate synthase confirmed by enzyme analysis or DNA mutation analysis**

   or

4. **Patient awaiting confirmation of hyperammonemia due to the deficiency hepatic enzyme-N-acetylglutamate synthase enzyme analysis or DNA mutation analysis (approval will be limited to three (3) months)**

   and

5. **Dose requested is between 100 mg/kg/day-250 mg/kg/day and is rounded to the nearest 100 mg for adults. (For pediatric doses, the tablet should be dissolved in 2.5 ml of water to yield a concentration of 80 mg/ml.)**

PI Orphan Europe SARl
Paris, France
US Approval 2010

WV DUR Board Review
3/2/2011