

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 1224-2
Program	Prior Authorization/Notification
Medication	Carbaglu™ (carglumic acid)
P&T Approval Date	7/2017, 7/2018
Effective Date	10/1/2018; Oxford only: 10/1/2018

1. Background

Carbaglu (carglumic acid) is a Carbamoyl Phosphate Synthetase 1 (CPS 1) activator indicated for maintenance therapy in pediatric and adult patients for chronic hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS). Carbaglu is also indicated as an adjunctive therapy in pediatric and adult patients for the treatment of acute hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS). During acute hyperammonemic episodes concomitant administration of Carbaglu with other ammonia lowering therapies such as alternate pathway medications, hemodialysis, and dietary protein restriction are recommended.¹

Coverage for Carbaglu will be provided for patients who meet the following criteria:

2. Coverage Criteria:

A. Initial Authorization

1. **Carbaglu** will be approved based on the following criterion:

- a. Diagnosis of N-acetylglutamate synthase (NAGS) deficiency

Authorization will be issued for 12 months.

B. Reauthorization

1. **Carbaglu** will be approved based on the following criterion:

- a. Documentation of positive clinical response to Carbaglu therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

N/A

4. References:

1. Carbaglu® [package insert], Memphis, TN: Accredo Health Group, Inc.; November 2017.

Program	Prior Authorization/Notification – Carbaglu (carglumic acid)
Change Control	
7/2017	New program.
7/2018	Annual review with no change to coverage criteria. Updated reference.