

Clinical Pharmacy Program Guidelines for Carbaglu

Program	Prior Authorization
Medication	Carbaglu™ (carglumic acid)
Issue Date	7/2017
Pharmacy and Therapeutics Approval Date	7/2017
Effective Date	9/2017

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

2. Coverage Criteria:

<p>A. <u>Initial Authorization</u></p> <p>1. Carbaglu will be approved based on the following criteria:</p> <p style="padding-left: 40px;">a. Diagnosis of N-acetylglutamate synthase (NAGS) deficiency</p> <p style="padding-left: 40px;">Authorization will be issued for 12 months.</p> <p>B. <u>Reauthorization</u></p> <p>1. Carbaglu will be approved based on the following criteria:</p> <p style="padding-left: 40px;">a. Documentation of positive clinical response to Carbaglu therapy</p> <p style="padding-left: 40px;">Authorization will be issued for 12 months.</p>

3. References:

1. Carbaglu® [package insert], Memphis, TN: Accredo Health Group, Inc. ; August 2013.

Program	Prior Authorization
Change Control	
Date	Change
7/2017	New program