

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1224-9
Program	Prior Authorization/Notification
Medication	Carbaglu® (carglumic acid)
P&T Approval Date	7/2017, 7/2018, 7/2019, 7/2020, 7/2021, 7/2022, 7/2023, 7/2024, 7/2025
Effective Date	10/1/2025

1. Background

Carbaglu (carglumic acid) is a carbamoyl phosphate synthetase 1 (CPS 1) activator indicated in pediatric and adult patients as maintenance therapy for the treatment of chronic hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency, adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to NAGS deficiency, and adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA).

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

2. Coverage Criteria^a:

A. Initial Authorization

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

a. Diagnosis of hyperammonemia due to **one** of the following:

- (1) N-acetylglutamate synthase (NAGS) deficiency
- (2) Propionic acidemia (PA)
- (3) Methylmalonic acidemia (MMA)

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.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limitations may be in place.

4. References:

1. Carbaglu® [package insert], Lebanon, NJ: Recordati Rare Diseases Inc.; January 2024.

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.
7/2019	Annual review with no change to coverage criteria.
7/2020	Annual review with no change to coverage criteria. Updated background and reference.
7/2021	Annual review. Added criteria for hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA). Updated background and reference.
7/2022	Annual review with no change to coverage criteria. Added state mandate disclaimer.
7/2023	Annual review. Updated reference.
7/2024	Annual review with no changes to coverage criteria. Updated reference.
7/2025	Annual review with no changes to coverage criteria.