

Carbaglu (carglumic acid)

Coverage Criteria:

Reserved for use in:

1. The management of adult and pediatric patients with urea cycle disorders (UCDs) that cannot be managed by dietary protein restriction and amino acid supplementation;
2. When used in combination with dietary protein restriction;
3. When prescribed by a provider specializing in genetics and metabolism;
4. The patient and/or guardian has attested that they will adhere to the treatment plan; and
5. When prescribed according to the FDA-approved regimen.

Coverage Duration:

Initial approvals will be for 12 months.

Renewal Criteria:

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months, continued adherence to dietary protein restriction and improved markers of disease. These include but may not be limited to ammonia control and a reduction in the number of hyperammonemic crises.