

## Carglumic Acid

**Goal(s):**

- Ensure appropriate utilization of carglumic acid in FDA-approved indications
- Incorporate 2-step review process for drugs on the high-cost drug carve-out list.

**Length of Authorization:** Up to 12 months

**Requires PA:**

- CARBAGLU (carglumic acid) tablets for oral suspension

**Covered Populations:** FFS and CCO enrolled patients starting 1/1/26

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at [www.orpdl.org](http://www.orpdl.org)
- Searchable site for Oregon FFS Drug Class listed at [www.orpdl.org/drugs/](http://www.orpdl.org/drugs/)

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is this a request for continuation of therapy?	<b>Yes:</b> Go to Renewal Criteria	<b>No:</b> Go to #3
3. Is this an FDA approved indication?	<b>Yes:</b> Go to #4	<b>No:</b> Pass to RPh. Deny; medical appropriateness
4. Is the request for therapy to treat hyperammonemia due to N-acetyl glutamate synthetase (NAGS) deficiency treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA)?	<b>Yes:</b> Go to #5	<b>No:</b> Pass to RPh. Deny; medical appropriateness
5. Has the diagnosis been confirmed by genetic testing?	<b>Yes:</b> Go to #6	<b>No:</b> Pass to RPh. Deny; medical appropriateness
6. Is the patient on a protein restricted diet?	<b>Yes:</b> Go to #7	<b>No:</b> Pass to RPh. Deny; medical appropriateness
7. Have baseline ammonia levels been documented?	<b>Yes:</b> Go to #8  Document date and results  _____	<b>No:</b> Pass to RPh. Deny; medical appropriateness

## Approval Criteria

8. Is the medication prescribed by or in consultation with a provider with expertise in managing urea cycle disorders or organic acidemias?	<b>Yes:</b> Go to #9	<b>No:</b> Pass to RPh. Deny; medical appropriateness
9. Is the request for a preferred product?	<b>Yes:</b> Pass to RPh. Pend; Refer to DMAP for secondary review.  Duration: Approvals cover up to 12 months.	<b>No:</b> Pass to RPh. Deny; medical appropriateness

## Renewal Criteria

1. Is the request to renew therapy for treatment of hyperammonemia due to NAGS deficiency, or treatment of acute hyperammonemia due to PA or MMA?	<b>Yes:</b> Go to #2	<b>No:</b> Pass to RPh. Deny; medical appropriateness
2. Has the patient's condition improved as assessed by the prescribing provider and the provider attests to patient's improvement?	<b>Yes:</b> Pass to RPh. Pend; Refer to DMAP for secondary review.  Duration: Approvals cover up to 12 months.	<b>No:</b> Pass to RPh. Deny; medical appropriateness

P&T/DUR Review: 12/25 (DM)

Implementation: 1/1/26