

## I. Requirements for Prior Authorization of Urea Cycle Disorder Agents

### A. Prescriptions That Require Prior Authorization

Prescriptions for Urea Cycle Disorder Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Urea Cycle Disorder Agent. See the Preferred Drug List (PDL) for the list of preferred Urea Cycle Disorder Agents at: <https://papdl.com/preferred-drug-list>.

### B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Urea Cycle Disorder Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Urea Cycle Disorder Agent by or in consultation with a physician who specializes in treating metabolic disorders; **AND**
2. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
3. Has chart documentation supporting the diagnosis (e.g., ammonia levels, genetic testing, enzyme assays, plasma amino acid/urine orotic acid analyses, progress notes); **AND**
4. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
5. For a non-preferred Urea Cycle Disorder Agent, has a documented history of therapeutic failure, contraindication, or intolerance to the preferred Urea Cycle Disorder Agent

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved

**FOR RENEWALS OF PRESCRIPTIONS FOR UREA CYCLE DISORDER AGENTS:** The determination of medical necessity of a request for renewal of a prior authorization for a Urea Cycle Disorder Agent that was previously approved will take into account whether the beneficiary:

1. Has documentation from the prescribing provider that the beneficiary had a positive clinical response to therapy; **AND**
2. Is prescribed the Urea Cycle Disorder Agent by or in consultation with a physician who specializes in treating metabolic disorders; **AND**
3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Urea Cycle Disorder Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

## UREA CYCLE DISORDER AGENTS PRIOR AUTHORIZATION FORM

<input type="checkbox"/> New request <input type="checkbox"/> Renewal request		# of pages: _____	Prescriber name:	
Name of office contact:			Specialty:	
Contact's phone number:			NPI:	State license #:
LTC facility contact/phone:			Street address:	
Beneficiary name:			Suite #:	City/state/zip:
Beneficiary ID#:	DOB:	Phone:	Fax:	
Medication will be billed via: <input type="checkbox"/> Pharmacy <input type="checkbox"/> Medical (Jcode: _____)			Place of Service: <input type="checkbox"/> Hospital <input type="checkbox"/> Provider's Office <input type="checkbox"/> Home <input type="checkbox"/> Other	

### CLINICAL INFORMATION

Refer to <https://papdl.com/preferred-drug-list> for a list of preferred and non-preferred drugs in this class.

Drug requested:	Strength/formulation:	
Directions:	Quantity:	Refills:
Diagnosis ( <u>submit documentation</u> ):	Diagnosis code ( <u>required</u> ):	
Is the medication being prescribed by or in consultation with a metabolic disorders specialist? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>Submit documentation of consultation.</i>		

### INITIAL requests

Is the beneficiary's diagnosis supported by any of the following? <i>Check all that apply.</i>		
<input type="checkbox"/> ammonia levels	<input type="checkbox"/> plasma amino acid/urine orotic acid analyses	<input type="checkbox"/> Yes <input type="checkbox"/> No <i>Submit documentation.</i>
<input type="checkbox"/> enzyme assays	<input type="checkbox"/> progress notes	
<input type="checkbox"/> genetic testing	<input type="checkbox"/> other ( <i>specify</i> ): _____	
Does the beneficiary have a history of trial and failure of or contraindication or intolerance to the preferred medication in this class? Refer to <a href="https://papdl.com/preferred-drug-list">https://papdl.com/preferred-drug-list</a> for a list of preferred and non-preferred drugs in this class. <input type="checkbox"/> Yes <input type="checkbox"/> No <i>Submit documentation.</i>		

### RENEWAL requests

Has the beneficiary experienced a positive clinical response since starting the requested medication? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>Submit documentation.</i>
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### PLEASE FAX COMPLETED FORM TO HIGHMARK WHOLECARE – PHARMACY DIVISION

Prescriber Signature:	Date:
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