Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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 PRESCRIPITONS 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

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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.

Gateway Health℠

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UREA CYCLE DISORDER AGENTS PRIOR AUTHORIZATION FORM

☐New request ☐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: ☐ Pharmacy ☐ Medical (Jcode:)		Place of Service: ☐ Hospital ☐ Provider's Office ☐ Home ☐ 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 (*submit documentation*):	Diagnosis code (*required*):	

Is the medication being prescribed by or in consultation with a metabolic disorders specialist? ☐Yes ☐No *Submit documentation of consultation.*

INITIAL requests

Is the beneficiary's diagnosis supported by any of the following? *Check all that apply.*

☐ammonia levels
☐enzyme assays
☐genetic testing
☐plasma amino acid/urine orotic acid analyses
☐progress notes
☐other *(specify)*: _____

☐Yes ☐No *Submit documentation.*

Does the beneficiary have a history of trial and failure of or contraindication or intolerance to the preferred medication in this class? *Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.* ☐Yes ☐No *Submit documentation.*

RENEWAL requests

Has the beneficiary experienced a positive clinical response since starting the requested medication? ☐Yes ☐No *Submit documentation.*

PLEASE FAX COMPLETED FORM TO GATEWAY – PHARMACY DIVISION

Prescriber Signature:	**Date**: