pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
September 10, 2019	January 1, 2020	*See below

SUBJECT

Prior Authorization of Urea Cycle Disorder Agents – Pharmacy Services

BY

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Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994.

PURPOSE:

The purpose of this bulletin is to:

1. Inform providers of the addition of the Urea Cycle Disorder Agents class of drugs to the Preferred Drug List (PDL).
2. Issue new handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Urea Cycle Disorder Agents submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the Fee-for-Service delivery system. Providers rendering services in the MA managed care delivery system should address any questions related to Urea Cycle Disorder Agents to the appropriate managed care organization.

*01-19-57	09-19-53	27-19-51	
02-19-51	11-19-50	30-19-49	
03-19-50	14-19-49	31-19-56	
08-19-59	24-19-51	32-19-49	33-19-53

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type

Visit the Office of Medical Assistance Programs Web site at
http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm

BACKGROUND:

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed clinical literature and makes recommendations relating to the following:

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the PDL;
- Changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Classes of drugs to be added to or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the June 21, 2019, meeting, the P&T Committee recommended that the Department add the Urea Cycle Disorder Agents class of drugs to the PDL and proposed guidelines to determine medical necessity of Urea Cycle Disorder Agents. The requirement for prior authorization and guidelines to determine medical necessity of Urea Cycle Disorder Agents, as recommended by the P&T Committee, were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Urea Cycle Disorder Agents are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Urea Cycle Disorder Agents) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I

Pharmacy Prior Authorization General Requirements
http://www.dhs.pa.gov/provider/pharmacyservices/pharmacypriorauthorizationgeneralrequirements/index.htm

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
http://www.dhs.pa.gov/provider/pharmacyservices/drugsrequiringclinicalpriorauthorization/index.htm

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.

2. A Urea Cycle Disorder Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

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; **AND**

6. If a prescription for a Urea Cycle Disorder Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

   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; **AND**

4. If a prescription for a Urea Cycle Disorder Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

   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.

D. References

1. Haberle J, Boddaert N, et.al. Suggested guidelines for the diagnosis and management of urea cycle disorders. *Orphanet Journal of Rare Diseases*. 2012, 7:32.
2. Diaz G.A, Krivitzky L.S, et.al. Ammonia Control and Neurocognitive Outcome Among Urea Cycle Disorder Patients Treated with Glycerol Phenylbutyrate. *Hepatology*. 2013 June; 57(6): 2171–2179.
3. Smith W, Diaz G.A, et al. Ammonia control in children ages 2 months through 5 years with urea cycle disorders: comparison of sodium phenylbutyrate and glycerol phenylbutyrate. *Journal of Pediatrics*. 2013 June; 162(6): 1228–1234.
4. Ravicti Prescribing Information. Lake Forest, IL. Horizon Therapeutics, LLC.
5. Buphenyl Prescribing Information. Scottsdale, AZ: Ucyclyd Pharma Inc.; April 2009.