

ISSUE DATE September 11, 2019	EFFECTIVE DATE January 1, 2020	NUMBER *See below
SUBJECT Prior Authorization of Potassium Removing Agents – Pharmacy Services	BY  Sally A. Kozak, Deputy Secretary 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 Potassium Removing 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 Potassium Removing 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 Potassium Removing Agents to the appropriate managed care organization.

*01-19-47	09-19-43	27-19-41	33-19-43
02-19-41	11-19-40	30-19-39	
03-19-40	14-19-39	31-19-46	
08-19-49	24-19-41	32-19-39	

<p>COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:</p> <p>The appropriate toll-free number for your provider type</p> <p>Visit the Office of Medical Assistance Programs Web site at http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm</p>

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 Potassium Removing Agents class of drugs to the PDL and proposed guidelines to determine medical necessity of Potassium Removing Agents. The requirement for prior authorization and guidelines to determine medical necessity of Potassium Removing 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 Potassium Removing 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 Potassium Removing 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>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Potassium Removing Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Potassium Removing Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

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

1. 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**
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is prescribed the Potassium Removing Agent by or in consultation with a cardiologist or nephrologist; **AND**
5. Has documentation of recent serum potassium levels consistent with a diagnosis of hyperkalemia; **AND**
6. Has documented therapeutic failure of **all** of the following:
 - a. A low potassium diet,
 - b. A loop or thiazide diuretic, if clinically appropriate,
 - c. Discontinuation or dose reduction to the minimum effective dose of medications known to cause hyperkalemia;

AND

7. For a non-preferred Potassium Removing Agent, has a history of therapeutic failure, contraindication, or intolerance of the preferred Potassium Removing Agents. See the Preferred Drug List (PDL) for the list of preferred Potassium Removing Agents at: <https://papdl.com/preferred-drug-list>; **AND**
8. If a prescription for a Potassium Removing 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. 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>.

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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.

FOR RENEWALS OF PRESCRIPTIONS FOR POTASSIUM REMOVING AGENTS: The determination of medical necessity of requests for prior authorization of renewals of prescriptions for Potassium Removing Agents that were previously approved will take into account whether the beneficiary:

1. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
2. Is prescribed the Potassium Removing Agent by or in consultation with a cardiologist or nephrologist; **AND**
3. Has documentation of recent serum potassium levels demonstrating a positive clinical response to therapy; **AND**
4. If a prescription for a Potassium Removing 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. 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>.

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 the request for a prescription for a Potassium Removing 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. Dose and Duration of Therapy

Requests for prior authorization of Potassium Removing Agents will be approved as follows:

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1. Initial requests for prior authorization of Potassium Removing Agents will be approved for up to 3 months.
2. Renewals of requests for prior authorization of Potassium Removing Agents will be approved for up to 12 months.

E. References

1. Lokelma [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals; May 2018.
2. Mount, DB. Treatment and Prevention of Hyperkalemia in Adults. Sterns RH, Forman, JP eds. Waltham, MA: UpToDate Inc. Updated December 18, 2017. Accessed April 30, 2019.
3. Veltassa [package insert]. Redwood City, CA: Relypsa, Inc.; May 2018.