pennsylvania
DEPARTMENT OF HUMAN SERVICES

# MEDICAL ASSISTANCE BULLETIN

| ISSUE DATE | EFFECTIVE DATE | NUMBER |
|---|---|---|
| November 17, 2021 | January 3, 2022 | *See below |

**SUBJECT**

Prior Authorization of Immunosuppressives, Oral – 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: https://www.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx.

## PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Immunosuppressives, Oral submitted for prior authorization.

## SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of Immunosuppressives, Oral will be utilized in the fee-for-service delivery system and by the MA managed care organizations (MCOs) in Physical Health HealthChoices and Community HealthChoices. Providers rendering services in the MA managed care delivery system should address any questions related to the prior authorization of Immunosuppressives, Oral to the appropriate MCO.

## BACKGROUND:

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| *01-21-53 | 09-21-52 | 27-21-42 | 33-21-52 |
| 02-21-38 | 11-21-41 | 30-21-46 | |
| 03-21-38 | 14-21-41 | 31-21-55 | |
| 08-21-55 | 24-21-49 | 32-21-38 | |

**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 website at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.

The Department of Human Services' (Department) Drug Utilization Review (DUR) Board meets to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department's Prospective DUR and Retrospective DUR programs.

**DISCUSSION:**

During the November 3, 2021, meeting, the DUR Board recommended the following revisions to the guidelines to determine medical necessity of prescriptions for Immunosuppressives, Oral:

- Addition of a requirement for prior authorization for Immunosuppressives, Oral with a prescribed quantity that exceeds the quantity limit;
- Addition of a guideline that the Immunosuppressive, Oral is prescribed for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication;
- Addition of a guideline that the prescribed dose is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;
- Addition of a guideline that the beneficiary does not have a contraindication to the requested medication;
- Addition of a guideline that addresses the recent FDA approval of Lupkynis (voclosporin) for the treatment of lupus nephritis; and
- Addition of a guideline that Immunosuppressives, Oral are subject to the guidelines in the Quantity Limits Chapter.

The revisions to the guidelines to determine medical necessity of prescriptions for Immunosuppressives, Oral submitted for prior authorization, as recommended by the DUR Board, 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 Immunosuppressives, Oral 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 Immunosuppressives, Oral) 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 and products 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
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx

# I. Requirements for Prior Authorization of Immunosuppressives, Oral

## A. Prescriptions That Require Prior Authorization

Prescriptions for Immunosuppressives, Oral that meet any of the following conditions must be prior authorized:

1. A non-preferred Immunosuppressive, Oral. See the Preferred Drug List (PDL) for the list of preferred Immunosuppressives, Oral at: https://papdl.com/preferred-drug-list.

2. An Immunosuppressive, Oral 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: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

## B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Immunosuppressive, Oral, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Immunosuppressive, Oral for the treatment of 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 prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Does not have a contraindication to the requested medication; **AND**

4. For Lupkynis (voclosporin), **all** of the following:

   a. For the treatment of lupus nephritis, has a diagnosis of active lupus nephritis that is confirmed by a kidney biopsy unless a kidney biopsy is not medically advisable,
   b. Is prescribed Lupkynis (voclosporin) by or in consultation with an appropriate specialist (e.g., nephrologist, rheumatologist),
   c. Is prescribed Lupkynis (voclosporin) in combination with background immunosuppressive therapy as tolerated,
   d. Is not prescribed Lupkynis (voclosporin) in combination with cyclophosphamide or Benlysta (belimumab);

   **AND**

5. For all other non-preferred Immunosuppressives, Oral, **one** of the following:

a. Has a documented history of therapeutic failure of or a contraindication or an intolerance to the preferred Immunosuppressives, Oral approved or medically accepted for the beneficiary's diagnosis
b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Immunosuppressive, Oral;

**AND**

6. If a prescription for an Immunosuppressive, Oral is for 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 listed above but, in the professional judgment 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 an Immunosuppressive, Oral. 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. Lupkynis [package insert]. Rockville, MD: Aurinia Pharma U.S., Inc. January 2021.
2. Falk RJ, Dall'Era M, Appel GB. Lupus nephritis: Initial and subsequent therapy for focal or diffuse lupus nephritis. In: UpToDate [internet database]. Glassock RJ, Rovin BH, Lam AQ, Ramirez Curtis M, eds. Waltham, MA: UpToDate Inc. Updated September 15, 2021. Accessed October 11, 2021.
3. Falk RJ, Dall'Era M, Appel GB. Lupus nephritis: Treatment of focal or diffuse lupus nephritis resistant to initial therapy. In: UpToDate [internet database]. Glassock RJ, Rovin BH, Lam AQ, Ramirez Curtis M, eds. Waltham, MA: UpToDate Inc. Updated October 14, 2021. Accessed October 26, 2021.
4. Fanouriakis A, Kostopoulou M, Cheema K, et al. 2019 update of the Joint European League Against Rheumatism and European Renal Association – European Dialysis and Transplant Association (EULAR/ERA-EDTA) recommendations for the management of lupus nephritis. Ann Rheum Dis. 2020;79:713-723.
5. Tice JA, Mandrik O, Thokala P, et al. Voclosporin and belimumab for lupus nephritis: Effectiveness and value; evidence report. Institute for Clinical and Economic review, April

16, 2021. https://icer.org/wp-content/uploads/2020/11/ICER_Lupus-Nephritis_Final-Evidence-Report_041621.pdf

6. Rovin BH, Adler SG, Barratt J, et al. KDIGO 2021 clinical practice guideline for the management of glomerular diseases. Kidney International. 2021;100(4S):S1-S276.