Pennsylvania
Department of Human Services

Medical Assistance BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 14, 2025	January 5, 2026	*See below

SUBJECT	BY
Prior Authorization of Immunosuppressives, Oral – Pharmacy Services	Sally 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: https://www.pa.gov/en/agencies/dhs/resources/for-providers/provider-enrollment-information/provider-enrollment-documents.html.

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 and managed care delivery systems. Providers rendering services to MA beneficiaries in the managed care delivery system should address any questions related to the prior authorization of Immunosuppressives, Oral to the appropriate managed care organization.

BACKGROUND/DISCUSSION:

The Department of Human Services (Department) is updating the medical necessity guidelines for Immunosuppressives, Oral to clarify that requests for a non-preferred Immunosuppressive, Oral will consider the availability of therapeutically equivalent brands and generics. There are no other changes to the medical necessity guidelines.

*01-26-24	09-26-24	27-26-24	33-26-24
02-26-24	11-26-24	30-26-24	
03-26-24	14-26-24	31-26-24	
08-26-24	24-26-24	32-26-24	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

Fee-for-Service Provider Service Center: 1-800-537-8862

Visit the Office of Medical Assistance Programs website at:
https://www.pa.gov/en/agencies/dhs/departments-offices/omap-info.html

The revisions to the guidelines to determine medical necessity of prescriptions for Immunosuppressives, Oral 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.pa.gov/en/agencies/dhs/resources/pharmacy-services/pharmacy-prior-authorization-general-requirements.html

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/clinical-guidelines.html

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.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html.

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 drug; **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 (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred);

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. April 2024.
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.
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.