Clinical Policy: Immunosuppressives, Oral

Reference Number: PHW.PDL.229
Effective Date: 01/01/2020
Last Review Date: 11/2025

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Oral Immunosuppressive Agents are **medically necessary** when the following criteria are met:

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.

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 member:

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 member'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 PA.CP.PMN.59 Quantity Limit Override.

   NOTE: If the member 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 member, 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 member.

D. **Approval Duration: 12 months**

E. 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.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021 annual review: no changes.	01/2021
Q1 2022: revised according to DHS revisions effective 01/03/2022.	10/2021
Q1 2023 annual review: no changes.	11/2022
Q1 2024 annual review: no changes.	11/2023
Q1 2025 annual review: no changes.	11/2024
Q1 2026: policy revised according to DHS revisions effective 01/05/2026.	11/2025