

ISSUE DATE November 10, 2021	EFFECTIVE DATE January 3, 2022	NUMBER *See below
SUBJECT Prior Authorization of Immunomodulators, Atopic Dermatitis – 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: <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 Immunomodulators, Atopic Dermatitis 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 Immunomodulators, Atopic Dermatitis 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 Immunomodulators, Atopic Dermatitis to the appropriate MCO.

BACKGROUND:

*01-21-30	09-21-29	27-21-21	33-21-29
02-21-17	11-21-19	30-21-24	
03-21-17	14-21-20	31-21-32	
08-21-32	24-21-27	32-21-17	

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) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed medical literature and recommends the following:

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the Preferred Drug List (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 September 15, 2021, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Immunomodulators, Atopic Dermatitis:

- Revision of the guidelines for Eucrisa (crisaborole) to apply to all topical phosphodiesterase type 4 (PDE4) inhibitors in this class;
- Addition of a guideline for topical PDE4 inhibitors that the treatment of the beneficiary's diagnosis with a topical PDE4 inhibitor is consistent with U.S. Food and Drug Administration-approved package labeling or medical literature;
- Specification that for topical PDE4 inhibitors, therapeutic failure of or a contraindication or an intolerance to a topical calcineurin inhibitor will take into account the beneficiary's diagnosis; and
- Addition of a requirement for prior authorization and medical necessity guidelines for topical Janus kinase inhibitors.

The revisions to the guidelines to determine medical necessity of prescriptions for Immunomodulators, Atopic Dermatitis submitted for prior authorization, 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 Immunomodulators, Atopic Dermatitis 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 Immunomodulators, Atopic Dermatitis) 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

<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>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Immunomodulators, Atopic Dermatitis

A. Prescriptions That Require Prior Authorization

Prescriptions for Immunomodulators, Atopic Dermatitis that meet the following conditions must be prior authorized.

1. A non-preferred Immunomodulator, Atopic Dermatitis. See Preferred Drug List (PDL) for the list of preferred Immunomodulators, Atopic Dermatitis at: <https://papdl.com/preferred-drug-list>.
2. A topical phosphodiesterase type 4 (PDE4) inhibitor.
3. A topical Janus kinase (JAK) inhibitor.

B. Review of Documentation for Medical Necessity

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

1. For Dupixent (dupilumab), see the provider handbook pages in the SECTION II chapter related to Dupixent (dupilumab); **OR**
2. For a non-preferred topical calcineurin inhibitor, has a history of therapeutic failure of or a contraindication or an intolerance of the preferred topical calcineurin inhibitors; **AND**
3. For a topical PDE4 inhibitor, **all** of the following:
 - a. Is prescribed the topical PDE4 inhibitor 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,
 - b. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
 - c. Has a history of therapeutic failure of or a contraindication or an intolerance to a topical calcineurin inhibitor approved or medically accepted for the treatment of the beneficiary's diagnosis;

AND

4. For a topical JAK inhibitor, **all** of the following:
 - a. Is prescribed the topical JAK inhibitor for the treatment of a diagnosis that is indicated in the FDA-approved package labeling OR a medically accepted indication,
 - b. Is age-appropriate according to FDA-approved package labeling, nationally recognized

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- compendia, or peer-reviewed medical literature,
- c. Has a history of therapeutic failure of or a contraindication or an intolerance to a topical corticosteroid approved or medically accepted for the treatment of the beneficiary's diagnosis,
 - d. Has a history of therapeutic failure of or a contraindication or an intolerance to a topical calcineurin inhibitor approved or medically accepted for the treatment of the beneficiary's diagnosis.

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 Immunomodulator, Atopic Dermatitis. 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.