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SUBJECT Prior Authorization of Immunomodulators, Atopic Dermatitis – Pharmacy Services		BY  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/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 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 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 Immunomodulators, Atopic Dermatitis to the appropriate managed care organization.

BACKGROUND:

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 and products in therapeutic classes already included on the Statewide Preferred Drug List (PDL).

*01-25-16	09-25-16	27-25-16	33-25-16
02-25-16	11-25-16	30-25-16	
03-25-16	14-25-16	31-25-16	
08-25-17	24-25-16	32-25-16	

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>

- Changes to the statuses of drugs and products on the Statewide PDL from preferred to non-preferred and non-preferred to preferred.
- Therapeutic classes of drugs and products to be added to or deleted from the Statewide PDL.
- New quantity limits.
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the September 10, 2024, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Immunomodulators, Atopic Dermatitis:

- Addition of guidelines for a non-preferred topical phosphodiesterase type 4 inhibitor.
- Addition of guidelines for a non-preferred topical Janus kinase inhibitor.
- Addition of a guideline to the requests for renewal of prior authorization section related to requests for a non-preferred targeted systemic Immunomodulator, Atopic Dermatitis with a therapeutically equivalent brand or generic, interchangeable biosimilar, or brand or unbranded biologic that is preferred on the PDL.

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 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>

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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 the Preferred Drug List (PDL) for the list of preferred Immunomodulators, Atopic Dermatitis at: <https://papdl.com/preferred-drug-list>.
2. An Immunomodulator, Atopic Dermatitis 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>.
3. A topical phosphodiesterase type 4 (PDE4) inhibitor.
4. A topical Janus kinase (JAK) inhibitor.
5. A targeted systemic Immunomodulator, Atopic Dermatitis (e.g., Adbry [tralokinumab], Cibinqo [abrocitinib], Rinvoq [upadacitinib]).

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 prior authorization guideline related to Dupixent (dupilumab); **OR**
2. Is prescribed the Immunomodulator, Atopic Dermatitis 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**
3. Is age-appropriate according to FDA-approved package labeling, national compendia, or peer-reviewed medical literature; **AND**
4. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
5. Does not have a contraindication to the requested drug; **AND**
6. For a non-preferred topical calcineurin inhibitor, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical calcineurin inhibitors; **AND**

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7. For a topical PDE4 inhibitor, **all** of the following:
- a. Has a history of therapeutic failure of or a contraindication or an intolerance to a four-week trial of a topical corticosteroid approved or medically accepted for the treatment of the beneficiary's diagnosis,
 - b. Has a history of therapeutic failure of or a contraindication or an intolerance to an eight-week trial of a topical calcineurin inhibitor approved or medically accepted for the treatment of the beneficiary's diagnosis,
 - c. For a non-preferred topical PDE4 inhibitor, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical PDE4 inhibitors approved or medically accepted for the beneficiary's diagnosis;

AND

8. For a topical JAK inhibitor, **all** of the following:
- a. Has a history of therapeutic failure of or a contraindication or an intolerance to a four-week trial of a topical corticosteroid approved or medically accepted for the treatment of the beneficiary's diagnosis,
 - b. Has a history of therapeutic failure of or a contraindication or an intolerance to an eight-week trial of a topical calcineurin inhibitor approved or medically accepted for the treatment of the beneficiary's diagnosis,
 - c. For a non-preferred topical JAK inhibitor, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical JAK inhibitors approved or medically accepted for the beneficiary's diagnosis;

AND

9. For all other non-preferred topical Immunomodulators, Atopic Dermatitis, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical Immunomodulators, Atopic Dermatitis approved or medically accepted for the beneficiary's diagnosis; **AND**
10. For a targeted systemic Immunomodulator, Atopic Dermatitis, **all** of the following:
- a. Is prescribed the targeted systemic Immunomodulator, Atopic Dermatitis by or in consultation with an appropriate specialist (e.g., dermatologist),
 - b. If currently using a different targeted systemic Immunomodulator, Atopic Dermatitis, will discontinue the other targeted systemic Immunomodulator, Atopic Dermatitis prior to starting the requested targeted systemic Immunomodulator, Atopic Dermatitis,
 - c. For treatment of moderate to severe chronic atopic dermatitis, has a history of therapeutic failure of or a contraindication or an intolerance to **both** of the following:

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- i. **One** of the following:
 - a) For treatment of the face, skin folds, or other critical areas, a four-week trial of a low-potency topical corticosteroid
 - b) For treatment of other areas, a four-week trial of a medium-potency or higher topical corticosteroid
- ii. An eight-week trial of a topical calcineurin inhibitor,
- d. For treatment of all other diagnoses, has a history of therapeutic failure of or a contraindication or an intolerance to first-line therapy(ies) if applicable according to current consensus treatment guidelines,
- e. For an oral JAK inhibitor, **one** of the following:
 - i. Has a history of therapeutic failure of at least one biologic if recommended for the beneficiary's diagnosis in the FDA-approved package labeling for the requested oral JAK inhibitor,
 - ii. Has a contraindication or an intolerance to biologics if recommended for the beneficiary's diagnosis in the FDA-approved package labeling for the requested oral JAK inhibitor,
 - iii. Has a current history (within the past 90 days) of being prescribed an oral JAK inhibitor,
- f. For a non-preferred targeted systemic Immunomodulator, Atopic Dermatitis, **one** of the following:
 - i. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred targeted systemic Immunomodulators, Atopic Dermatitis approved or medically accepted for the beneficiary's diagnosis
 - ii. Has a current history (within the past 90 days) of being prescribed the same targeted systemic Immunomodulator, Atopic Dermatitis (does not apply to non-preferred brands when the therapeutically equivalent generic, interchangeable biosimilar, or unbranded biologic is preferred or to non-preferred generics, interchangeable biosimilars, or unbranded biologics when the therapeutically equivalent brand, interchangeable brand, or brand biologic is preferred);

AND

- 11. If a prescription for an Immunomodulator, Atopic Dermatitis 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

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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.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR AN IMMUNOMODULATOR, ATOPIC DERMATITIS: The determination of medical necessity of a request for renewal of a prior authorization for an Immunomodulator, Atopic Dermatitis that was previously approved will take into account whether the beneficiary:

1. Has documented evidence of improvement of disease severity; **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 a non-preferred topical calcineurin inhibitor, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical calcineurin inhibitors; **AND**
5. For a non-preferred topical PDE4 inhibitor, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical PDE4 inhibitors approved or medically accepted for the beneficiary's diagnosis; **AND**
6. For a non-preferred topical JAK inhibitor, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical JAK inhibitors approved or medically accepted for the beneficiary's diagnosis; **AND**
7. For all other non-preferred topical Immunomodulators, Atopic Dermatitis, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical Immunomodulators, Atopic Dermatitis approved or medically accepted for the beneficiary's diagnosis; **AND**
8. For a targeted systemic Immunomodulator, Atopic Dermatitis, **both** of the following:
 - a. Is prescribed the targeted systemic Immunomodulator, Atopic Dermatitis by or in consultation with an appropriate specialist (e.g., dermatologist)
 - b. For a non-preferred targeted systemic Immunomodulator, Atopic Dermatitis with a therapeutically equivalent brand or generic, interchangeable biosimilar, or brand or unbranded biologic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic, interchangeable biosimilar, or brand or unbranded biologic that would not be expected to occur with the requested drug;

AND

9. If a prescription for an Immunomodulator, Atopic Dermatitis is for a quantity that exceeds

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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 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.

D. References

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