

PA DEPARTMENT OF HUMAN SERVICES
MAAC BRIEFING DOCUMENT
IMMUNOMODULATORS, DERMATOLOGICS

Proposed Effective Date: January 5, 2026

Revisions are noted with a ~~strikethrough~~ for deletions and **bold and underline** for additions.

I. Requirements for Prior Authorization of Immunomodulators, ~~Atopic Dermatitis~~ **Dermatologics**

A. Revisions to Prescriptions That Require Prior Authorization

Prescriptions for Immunomodulators, ~~Atopic Dermatitis~~ **Dermatologics** that meet the following conditions must be prior authorized:

1. A non-preferred Immunomodulators, ~~Atopic Dermatitis~~ **Dermatologic**. See the Preferred Drug List (PDL) for the list of preferred Immunomodulators, ~~Atopic Dermatitis~~ **Dermatologics** at: <https://papdl.com/preferred-drug-list>.
2. An Immunomodulators, ~~Atopic Dermatitis~~ **Dermatologic** 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 Janus kinase (JAK) inhibitor (**e.g., delgocitinib, ruxolitinib**).
4. A topical phosphodiesterase type 4 (PDE4) inhibitor (**e.g., crisaborole, roflumilast**).
5. **A topical aryl hydrocarbon receptor (AhR) agonist (e.g., tapinarof)**.
6. A targeted systemic Immunomodulators, ~~Atopic Dermatitis~~ **Dermatologic** (e.g., abrocitinib, **nemolizumab**, tralokinumab, upadacitinib).

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Immunomodulators, ~~Atopic Dermatitis~~ **Dermatologic**, 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 Immunomodulators, ~~Atopic Dermatitis~~ **Dermatologic** 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**

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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**
7. For a topical PDE4 inhibitor (**e.g., crisaborole, roflumilast**), ~~all~~ **both** of the following:
 - a. **One of the following:**
 - i. **For treatment of psoriasis or seborrheic dermatitis, see the prior authorization guideline for Antipsoriatics, Topical,**
 - ii. **For treatment of atopic dermatitis, has a history of therapeutic failure of or a contraindication or an intolerance to both 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,
 - iii. **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 consensus treatment guidelines**
 - b. 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 (**e.g., ruxolitinib**), ~~all~~ **both** of the following:
 - a. **One of the following:**
 - i. **For treatment of atopic dermatitis, has a history of therapeutic failure of or a contraindication or an intolerance to both 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

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- 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,
- ii. **For treatment of chronic hand eczema, has a history of therapeutic failure of or a contraindication or an intolerance to both of the following:**
 - a) **A four-week trial of a topical corticosteroid approved or medically accepted for the treatment of the beneficiary's diagnosis**
 - b) **An eight-week trial of a topical calcineurin inhibitor approved or medically accepted for the treatment of the beneficiary's diagnosis,**
- iii. **For treatment of vitiligo, has a history of therapeutic failure of or a contraindication or an intolerance to both of the following:**
 - a) **A four-week trial of a topical corticosteroid approved or medically accepted for the treatment of the beneficiary's diagnosis**
 - b) **An eight-week trial of a topical calcineurin inhibitor approved or medically accepted for the treatment of the beneficiary's diagnosis,**
- iv. **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 consensus treatment guidelines**
- b. 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 a topical AhR agonist (e.g., tapinarof), both of the following:**
 - a. **One of the following:**
 - i. **For treatment of psoriasis, see the prior authorization guideline for Antipsoriatics, Topical,**
 - ii. **For treatment of atopic dermatitis, has a history of therapeutic failure of or a contraindication or an intolerance to both of the following:**
 - a) **A four-week trial of a topical corticosteroid approved or medically accepted for the treatment of the beneficiary's diagnosis**
 - b) **A eight-week trial of a topical calcineurin inhibitor approved or medically accepted for the treatment of the beneficiary's diagnosis,**
 - iii. **For treatment of all other diagnoses, has a history of therapeutic failure of or a**

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contraindication or an intolerance to first line therapy(ies) if applicable according to consensus treatment guidelines

- b. **For a non-preferred topical AhR agonist, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical AhR agonists approved or medically accepted for the beneficiary's diagnosis;**

AND

10. For all other non-preferred topical Immunomodulators, ~~Atopic Dermatitis~~ **Dermatologics**, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical Immunomodulators, ~~Atopic Dermatitis~~ **Dermatologics** approved or medically accepted for the beneficiary's diagnosis; **AND**
11. For a targeted systemic Immunomodulators, ~~Atopic Dermatitis~~ **Dermatologic**, all of the following:
- a. Is prescribed the targeted systemic Immunomodulators, ~~Atopic Dermatitis~~ **Dermatologic** by or in consultation with an appropriate specialist (e.g., dermatologist),
- b. If currently using a different targeted systemic Immunomodulators, ~~Atopic Dermatitis~~ **Dermatologic**, will discontinue the other targeted systemic Immunomodulators, ~~Atopic Dermatitis~~ **Dermatologic** prior to starting the requested targeted systemic Immunomodulators, ~~Atopic Dermatitis~~ **Dermatologic**,
- c. For treatment of ~~moderate to severe~~ chronic atopic dermatitis, **both of the following:**
- i. **Has atopic dermatitis associated with at least one of the following:**
- a) **A body surface area of 10% or greater that is affected,**
- b) **Involvement of critical areas (e.g., face, feet, genitals, hands, intertriginous areas, scalp),**
- c) **Significant disability or impairment of physical, mental, or psychosocial functioning**
- ii. Has a history of therapeutic failure of or a contraindication or an intolerance to **both** of the following:
- a) ~~One~~ of the following:
- (i) ~~For treatment of the face, skin folds, or other critical areas, a four-week trial of a low-potency topical corticosteroid~~
- (ii) ~~For treatment of other areas, a four-week trial of a medium-potency or higher-topical corticosteroid~~
- b) **A four-week trial of a topical corticosteroid approved or medically accepted**

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for the treatment of the beneficiary's diagnosis

- c) An eight-week trial of a topical calcineurin inhibitor **approved or medically accepted for the treatment of the beneficiary's diagnosis**,
- d. **For treatment of prurigo nodularis, both of the following:**
 - i. **Has a history of pruritis lasting at least six weeks**
 - ii. **Has prurigo nodularis associated with at least one of the following:**
 - a) **Greater than or equal to 20 nodular lesions**
 - b) **Significant disability or impairment of physical, mental, or psychosocial functioning,**
- e. 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,
- f. 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,
- g. For a non-preferred targeted systemic Immunomodulators, ~~Atopic Dermatitis~~ **Dermatologic**, **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~~ **Dermatologics** 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 Immunomodulators, ~~Atopic Dermatitis~~ **Dermatologic** (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) **(does not apply to non-preferred targeted systemic Immunomodulators, Dermatologics when a therapeutically equivalent brand/generic or corresponding biosimilar/brand biologic/unbranded biologic is preferred)**;

AND

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12. If a prescription for an Immunomodulators, ~~Atopic Dermatitis~~ **Dermatologic** 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.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR AN IMMUNOMODULATORS, ~~ATOPIG DERMATITIS~~ **DERMATOLOGIC**: The determination of medical necessity of a request for renewal of a prior authorization for an Immunomodulators, ~~Atopic Dermatitis~~ **Dermatologic** 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 a non-preferred topical AhR agonist, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical AhR agonists approved or medically accepted for the beneficiary's diagnosis; AND**
8. For all other non-preferred topical Immunomodulators, ~~Atopic Dermatitis~~ **Dermatologics**, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical Immunomodulators, ~~Atopic Dermatitis~~ **Dermatologics** approved or medically accepted for the beneficiary's diagnosis; **AND**
9. For a targeted systemic Immunomodulator, ~~Atopic Dermatitis~~ **Dermatologics**, **both** of the following:
 - a. Is prescribed the targeted systemic Immunomodulators, ~~Atopic Dermatitis~~

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- Dermatologic** by or in consultation with an appropriate specialist (e.g., dermatologist)
- b. For a non-preferred targeted systemic Immunomodulators, Atopic Dermatitis **Dermatologic** 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 **brand/generic or corresponding biosimilar/brand biologic/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/generic or corresponding biosimilar/brand biologic/unbranded biologic** that would not be expected to occur with the requested drug;

AND

10. If a prescription for an Immunomodulators, Atopic Dermatitis **Dermatologic** 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. Revisions to 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 Immunomodulators, Atopic Dermatitis **Dermatologic**. 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. Adbry [package insert]. Madison, NJ: LEO Pharma Inc.; ~~January 2022~~ **June 2024.**
2. Cibinqo [package insert]. New York, NY: Pfizer Labs; ~~February 2023~~ **December 2023.**
3. Eucrisa [package insert]. New York, NY: Pfizer Labs; April 2023.
4. **Nemluvio [package insert]. Dallas, TX: Galderma Laboratories, L.P. June 2025.**
5. Opzelura [package insert]. Wilmington, DE: Incyte Corporation; January 2023.
6. Rinvoq [package insert]. North Chicago, IL: AbbVie Inc.; ~~June 2023~~ **April 2025.**
7. **Vtama [package insert]. Long Beach, CA: Dermavant Sciences Inc. December 2024.**

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17. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. *J Am Acad Dermatol*. 2023;89(1):e1-e20.