# Clinical Policy: Immunomodulators, Dermatologics

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**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 Immunomodulators, Dermatologics are **medically necessary** when the following criteria are met:

## I. Requirements for Prior Authorization of Immunomodulators, Dermatologics

A. Prescriptions That Require Prior Authorization

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

1. A non-preferred Immunomodulator, Dermatologics.

2. An Immunomodulator, Dermatologics with a prescribed quantity that exceeds the quantity limit.

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 Immunomodulator, Dermatologic (e.g., abrocitinib, nemolizumab, tralokinumab, upadacitinib).

B. Review of Documentation for Medical Necessity

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

1. For Dupixent (dupilumab), refer to PHW.PDL.737.01 Dupixent (dupilumab); **OR**

2. Is prescribed the Immunomodulator, Dermatologicfor 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 of the preferred topical calcineurin inhibitors; **AND**

7. For a topical PDE4 inhibitor (e.g., crisaborole, roflumilast), 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) A 4-week trial of a topical corticosteroid approved or medically accepted for the treatment of the member's diagnosis,
            b) An 8-week trial of a topical calcineurin inhibitor approved or medically accepted for the treatment of the member'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 member's diagnosis;

    **AND**

8. For a topical JAK inhibitor (e.g., ruxolitinib), 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) A 4-week trial of a topical corticosteroid approved or medically accepted for the treatment of the member's diagnosis,
            b) An 8-week trial of a topical calcineurin inhibitor approved or medically accepted for the treatment of the member'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 member's diagnosis
b) An eight-week trial of a topical calcineurin inhibitor approved or medically accepted for the treatment of the member'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 member's diagnosis
b) An eight-week trial of a topical calcineurin inhibitor approved or medically accepted for the treatment of the member'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 member'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 PHW.PDL.147 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 member's diagnosis
b) An eight-week trial of a topical calcineurin inhibitor approved or medically accepted for the treatment of the member'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 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 member's diagnosis;

**AND**

10. For all other non-preferred topical Immunomodulators, Dermatologics, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical Immunomodulators, Dermatologics approved or medically accepted for the member's diagnosis; **AND**

11. For a targeted systemic Immunomodulator, Dermatologics, **all** of the following:

    a. Is prescribed the targeted systemic Immunomodulator, Dermatologics by or in consultation with an appropriate specialist (e.g., dermatologist),

    b. If currently using a different targeted systemic Immunomodulator, Dermatologics, will discontinue the other targeted systemic Immunomodulator, Dermatologics prior to starting the requested targeted systemic Immunomodulator, Dermatologics,

    c. For treatment of 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) A four-week trial of a topical corticosteroid approved or medically accepted for the treatment of the member's diagnosis
            b) An eight-week trial of a topical calcineurin inhibitor approved or medically accepted for the treatment of the member'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 member'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 member'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 Immunomodulator, 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, Dermatologic approved or medically accepted for the member's diagnosis
ii. Has a current history (within the past 90 days) of being prescribed the same targeted systemic Immunomodulator, Dermatologic (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);

12. If a prescription for an Immunomodulator, 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 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.

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

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 of 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 member'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 member'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 member's diagnosis; **AND**

8. For all other non-preferred topical Immunomodulators, Dermatologics, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical Immunomodulators, Dermatologics approved or medically accepted for the member's diagnosis; **AND**

9. For a targeted systemic Immunomodulator, Dermatologics, **both** of the following:

    a. Is prescribed the targeted systemic Immunomodulator, Dermatologics by or in consultation with an appropriate specialist (e.g., dermatologist);
    b. For a non-preferred targeted systemic Immunomodulator, Dermatologics with a therapeutically equivalent 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 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 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 Immunomodulator, 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 member.

D. **Approval Duration:**
- **New request: 6 months**
- **Renewal request: 12 months**

E. **References**

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15. Eleftheriadou V, Atkar R, Batchelor J, et al. British Association of Dermatologists guidelines for the management of people with vitiligo 2021. Br J Dermatol. 2022;186(1):18-29.
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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.

| 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 | 11/2021 |
| Q1 2023: revised according to DHS revisions effective 01/09/2023 | 10/2022 |
| Q1 2024: revised according to DHS revisions effective 01/08/2024 | 11/2023 |
| Q1 2025: policy revised according to DHS revisions effective 01/06/2025. | 11/2024 |