Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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. A topical phosphodiesterase type 4 (PDE4) inhibitor.
3. A topical Janus kinase (JAK) inhibitor.
4. 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 policy for 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**
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:

       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);

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 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;

   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.

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IMMUNOMODULATORS, ATOPIC DERMATITIS PRIOR AUTHORIZATION FORM *(form effective 1/8/2024)*

☐New request ☐Renewal request	# of pages: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		City/state/zip:	
Beneficiary ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Drug requested:	Strength:	Dosage form:	
Directions:		Quantity:	Refills:
Diagnosis (*submit documentation*):		Diagnosis code (*required*):	

Complete all sections that apply to the beneficiary and this request. *Check all that apply and submit documentation for each item.*

INITIAL requests

1. For a non-preferred topical calcineurin inhibitor:

☐Tried and failed or has a contraindication or an intolerance to the preferred topical calcineurin inhibitors *(Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.)*

2. For a topical JAK inhibitor (eg, Opzelura [ruxolitinib]) OR a topical PDE4 inhibitor (eg, Eucrisa [crisaborole]):

☐Tried and failed or has a contraindication or an intolerance to a 4-week trial of a topical corticosteroid approved or medically accepted for the beneficiary's diagnosis

☐Tried and failed or has a contraindication or an intolerance to an 8-week trial of a topical calcineurin inhibitor (eg, pimecrolimus, tacrolimus) approved or medically accepted for the beneficiary's diagnosis

3. For all other non-preferred TOPICAL Immunomodulators, Atopic Dermatitis:

☐Tried and failed or has a contraindication or an intolerance to the preferred topical Immunomodulators, Atopic Dermatitis approved or medically accepted for the beneficiary's diagnosis *(Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.)*

4. For a targeted systemic Immunomodulator, Atopic Dermatitis (eg, Adbry, Cibinqo, Rinvoq):

☐Is prescribed the medication by or in consultation with an appropriate specialist (eg, dermatologist)

☐**For the treatment of atopic dermatitis:** Tried and failed or has a contraindication or an intolerance to both of the following (*check all that apply):*

- ☐One of the following:
  - ☐For the face, skin folds, or other critical areas, a 4-week trial of a low-potency (or higher) topical corticosteroid
  - ☐For other body areas, a 4-week trial of a medium potency or higher topical corticosteroid
- ☐An 8-week trial of a topical calcineurin inhibitor (eg, pimecrolimus, tacrolimus)

☐**For the treatment of all other diagnoses – specify diagnosis:** _____

- ☐List other treatments tried (including start/stop dates, dose, outcomes, etc.): _____

_____

☐**For an oral JAK inhibitor (eg, Cibinqo, Rinvoq):**

- ☐Tried and failed at least one biologic as recommended in the JAK inhibitor's package labeling
- ☐Has a contraindication or an intolerance to biologics as recommended in the JAK inhibitor's package labeling

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☐ Is currently taking an oral JAK inhibitor

☐ **For a NON-PREFERRED targeted systemic Immunomodulator, Atopic Dermatitis:**

☐ Tried and failed or has a contraindication or intolerance to the preferred targeted systemic Immunomodulators, Atopic Dermatitis approved or medically accepted for the beneficiary's condition *(Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.)*

☐ Is currently using the requested non-preferred targeted systemic Immunomodulator, Atopic Dermatitis

- What is the date of the beneficiary's last dose? _____

RENEWAL requests

1. For a non-preferred topical calcineurin inhibitor:

☐ Has documented evidence of improvement of disease severity

☐ Tried and failed or has a contraindication or an intolerance to the preferred topical calcineurin inhibitors *(Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.)*

2. For a topical JAK inhibitor (eg, Opzelura [ruxolitinib]) OR a topical PDE4 inhibitor (eg, Eucrisa [crisaborole]):

☐ Has documented evidence of improvement of disease severity

3. For all other non-preferred TOPICAL Immunomodulators, Atopic Dermatitis:

☐ Has documented evidence of improvement of disease severity

☐ Tried and failed or has a contraindication or an intolerance to the preferred topical Immunomodulators, Atopic Dermatitis approved or medically accepted for the beneficiary's diagnosis *(Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.)*

4. For a targeted systemic Immunomodulator, Atopic Dermatitis (eg, Adbry, Cibinqo, Rinvoq):

☐ Has documented evidence of improvement of disease severity

☐ Is prescribed the medication by or in consultation with an appropriate specialist (eg, dermatologist)

PLEASE FAX COMPLETED FORM TO HIGHMARK WHOLECARE – PHARMACY DIVISION

Prescriber Signature:	**Date**: