Clinical Policy: Immunomodulators, Atopic Dermatitis

Reference Number: PHW.PDL.034
Effective Date: 01/01/2020
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Revision Log

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 Atopic Dermatitis Immunomodulators are **medically necessary** when the following criteria are met:

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.

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

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], Cibingo [abrocitinib], Rinvog [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 member:

1. For Dupixent (dupilumab), refer to PHW.PDL.737.01 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 medication; 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, **both** of the following:

   a. Has a history of therapeutic failure of or a contraindication or an intolerance to a 4-week trial of a topical corticosteroid approved or medically accepted for the treatment of the member's diagnosis,
   b. Has a history of therapeutic failure of or a contraindication or an intolerance to an 8-week trial of a topical calcineurin inhibitor approved or medically accepted for the treatment of the member's diagnosis;

   AND

8. For a topical JAK inhibitor, **both** of the following:

   a. Has a history of therapeutic failure of or a contraindication or an intolerance to a 4-week trial of a topical corticosteroid approved or medically accepted for the treatment of the member's diagnosis,
   b. Has a history of therapeutic failure of or a contraindication or an intolerance to an 8-week trial of a topical calcineurin inhibitor approved or medically accepted for the treatment of the member'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 member'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 4-week trial of a low-potency topical corticosteroid
      b) For treatment of other areas, a 4-week trial of a medium-potency or higher topical corticosteroid

   ii. An 8-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 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,

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 member'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 product is preferred);

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 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, 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 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 medication; **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 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 member's diagnosis; **AND**

6. For a targeted systemic Immunomodulator, Atopic Dermatitis, is prescribed the targeted systemic Immunomodulator, Atopic Dermatitis by or in consultation with an appropriate specialist (e.g., dermatologist); **AND**

7. 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, 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 member.

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

E. **References**

1. Adbry [package insert]. Madison, NJ: LEO Pharma Inc.; January 2022.
2. Cibinqo [package insert]. New York, NY: Pfizer Labs; February 2023.
3. Eucrisa [package insert]. New York, NY: Pfizer Labs; April 2023.
4. Opzelura [package insert]. Wilmington, DE: Incyte Corporation; January 2023.
5. Rinvoq [package insert]. North Chicago, IL: AbbVie Inc.; June 2023.
6. Sidbury R, Davis DM, Cohen DE, et al. Guidelines of care for the management of atopic dermatitis: Section 3. Management and treatment with phototherapy and systemic agents. J Am Acad Dermatol. 2014;71(2):327-49.
7. Boguniewicz M, Alexis AF, Beck LA, et al. Expert perspectives on management of moderate-to-severe atopic dermatitis: A multidisciplinary consensus addressing current and emerging therapies. J Allergy Clin Immunol Pract. 2017;5(6):1519-1531.
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9. Drucker AM, Ellis AG, Bohdanowicz M, et al. Systemic immunomodulatory treatment for patients with atopic dermatitis – a systemic review and network meta-analysis. JAMA Dermatol. 2020;156(6):659-667.
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15. Lio PA. Management of severe atopic dermatitis (eczema) in children. In: UpToDate [internet database]. Dellavalle RP, Levy ML, Fowler J, Corona R, eds. Waltham, MA: UpToDate. Updated June 28, 2022. Accessed August 1, 2023.

16. 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.
17. Grimes PE. Vitiligo: Management and prognosis. In: UpToDate [internet database]. Tsao H, Alexis AF, Corona R, eds. Waltham, MA: UpToDate Inc. Updated April 26, 2023. Accessed August 2, 2023.
18. 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
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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
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