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 beneficiary'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 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. For treatment of moderate to severe chronic atopic dermatitis, has a history of therapeutic failure of at least two of the following OR a contraindication or an intolerance to all 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,
   iii. Phototherapy in accordance with current consensus guidelines,
   iv. Conventional systemic immunosuppressives in accordance with current consensus guidelines (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil),

c. 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,
d. 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 other 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,
e. 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; **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 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 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 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 beneficiary'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 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 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; January 2022.
3. Eucrisa [package insert]. New York, NY: Pfizer Labs; March 2020.
4. Opzelura [package insert]. Wilmington, DE: Incyte Corporation; July 2022.
5. Rinvoq [package insert]. North Chicago, IL: AbbVie Inc.; April 2022.

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7. 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.
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14. Howe W. Treatment of atopic dermatitis (eczema). In: UpToDate [internet database]. Dellavalle RP, Levy ML, Fowler J, Corona R, eds. Waltham, MA: UpToDate Inc. Updated March 11, 2022. Accessed April 19, 2022.
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16. Spergel JM, 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 Inc. Updated August 9, 2021. Accessed April 20, 2022.
17. 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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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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