MEDICAL MUTUAL®

# Drug Policy

| Policy: | Topicals Agents for Atopic Dermatitis, Plaque Psoriasis, Seborrheic Dermatitis, and Vitiligo<br><br>• Eucrisa® (crisaborole) ointment<br>• Opzelura® (ruxolitinib) cream<br>• Vtama (tapinarof) cream<br>• Zoryve® (roflumilast) cream 0.3%, 0.15%, 0.05%<br>• Zoryve® (roflumilast) topical foam, 0.3% | **Annual Review Date:**<br>**11/20/2025**<br><br>**Last Revised Date:**<br>**11/20/2025** |
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## OVERVIEW

The American Academy of Dermatology (AAD) Guidelines of Care for the Management of **Atopic Dermatitis** in Adults with Topical Therapies (2023) recommend the use of topical corticosteroids and note that these products are commonly used as first-line topical treatment as they suppress the release of proinflammatory cytokines and target a variety of immune cells.[5] Topical calcineurin inhibitors (i.e., tacrolimus ointment and pimecrolimus cream) are noted to be a safe topical anti-inflammatory option, particularly if topical corticosteroid adverse events are of concern. Tacrolimus ointment is recommended for use in all adults with atopic dermatitis, while pimecrolimus cream is a recommended treatment option for patients with mild-to-moderate disease. Similarly, Eucrisa is a recommended treatment option for adults with mild-to-moderate atopic dermatitis. The AAD published a focused guideline update (2025) addressing several newer therapies.[8] These guidelines support the use of Zoryve 0.15% cream for adults with mild-to-moderate atopic dermatitis; the 0.05% strength is not addressed. Recommendations for the management of pediatric patients have not been updated. However, AAD guidelines from 2014 make similar recommendations regarding the use of topical corticosteroids and topical calcineurin inhibitors in pediatric patients.[6] Eucrisa and Zoryve cream are not addressed

The mainstay of treatment of **plaque psoriasis** is topical therapy, including corticosteroids, vitamin D analogs, calcineurin inhibitors, keratolytics (e.g., tazarotene), and combination therapies (e.g., a corticosteroid with a vitamin D analog).[3] Joint guidelines from the American Academy of Dermatology (AAD) and the Medical Board of the National Psoriasis Foundation (NPF) [2021] have been published for the management of psoriasis with topical therapies.[4] Neither Vtama nor Zoryve 0.3% cream are addressed in the guidelines. Use of a topical corticosteroid for up to 4 weeks is recommended for plaque psoriasis not involving intertriginous areas (strength of recommendation, A). A topical vitamin D analog can be used long-term (up to 52 weeks) for the treatment of psoriasis [strength of recommendation, A]. Guidelines also address use of topical calcineurin inhibitors, topical tazarotene, topical salicyclic acid, and phototherapy.

Guidelines from the International **Vitiligo** Task Force (2023) recommend topical corticosteroids, topical calcineurin inhibitors, and Opzelura as treatment options in patients with vitiligo.[6] Most of the studies to support the use of topical corticosteroids used potent to very potent corticosteroids applied topically daily for 3 to 6 months. Intermittent/alternating treatment schemes have been found to reduce adverse effects from topical corticosteroids and may enable longer treatment periods. Topical corticosteroids should be used with caution on the eyelids, axilla, and inguinal regions. Topical calcineurin inhibitors are often prescribed initially for up to 6 months. The guidelines note that topical corticosteroids and topical calcineurin inhibitors have not been found to be different in terms of efficacy; however, there are safety

differences. These therapies may be used in combination. The guidelines do not compare the efficacy of Opzelura with that of the other topical therapies.

**POLICY STATEMENT**

This policy involves the use of Topicals Agents for Atopic Dermatitis, Plaque Psoriasis, Seborrheic Dermatitis, and Vitiligo. Prior authorization is recommended for pharmacy benefit coverage of Topicals Agents for Atopic Dermatitis, Plaque Psoriasis, Seborrheic Dermatitis, and Vitiligo. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

**RECOMMENDED AUTHORIZATION CRITERIA**

Coverage of Eucrisa ointment, Opzelura cream, Vtama 1% cream, Zoryve 0.05% & 0.15% cream is recommended in those who meet the following criteria:

1. **Atopic Dermatitis**

   Approve if the patient meets all the following (A and B):

   **A)** Patient meets the following age criteria
   - **i.** Eucrisa: ≥ 3 months of age; OR
   - **ii.** Opzelura: ≥ 2 years of age; OR
   - **iii.** Vtama 1% cream: ≥ 2 years of age; OR
   - **iv.** Zoryve 0.05% cream: 2 to 5 years of age; OR
   - **v.** Zoryve 0.15% cream: ≥ 6 years of age; AND

   **B)** Patient meets ONE of the following (i or ii):
   - **i.** Patient meets ALL the following criteria (a, b, and c):
     - **a)** Patient has tried at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid; AND
       Note: Concomitant use of a topical corticosteroid with a topical calcineurin inhibitor would meet the requirement.
     - **b)** This topical corticosteroid was applied daily for at least 28 consecutive days; AND
     - **c)** Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescriber; OR
   - **ii.** Patients meets ALL of the following (i, ii, and iii)
     - **a)** Patient has tried at least one topical calcineurin inhibitor; AND
       Note: Examples of topical calcineurin inhibitors include tacrolimus ointment (Protopic®, generic) and pimecrolimus cream (Elidel®, generic). Concomitant use of a topical calcineurin inhibitor with a topical corticosteroid would meet the requirement.
     - **b)** This topical calcineurin inhibitor was applied daily for at least 28 consecutive days; AND
     - **c)** Inadequate efficacy was demonstrated with this topical calcineurin inhibitor, according to the prescriber.

**Initial Approval/ Extended Approval.**
**A)** *Initial Approval:* 8 weeks for Opzelura
1 year for Eucrisa, Vtama, and Zoryve 0.05% & 0.15% cream
**B)** *Extended Approval:* 8 weeks for Opzelura
1 year for Eucrisa, Vtama, and Zoryve 0.05% & 0.15% cream

Coverage of Vtama 1% cream, Zoryve 0.3% cream, Zoryve 0.3% foam is recommended in those who meet the following criteria:

**2. Plaque Psoriasis**
Approve if the patient meets all the following (A and B):
**A)** Patient meets the following age criteria
**i.** Vtama 1% cream: ≥ 18 years of age; OR
**ii.** Zoryve 0.3% cream: ≥ 6 years of age; OR
**iii.** Zoryve 0.3% foam: ≥ 12 years of age; AND
**B)** Patient meets both of the following (i and ii):
**i.** Patient meets ALL the following criteria (a, b, and c):
**a)** Patient has tried at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid; AND
Note: Concomitant use of a topical corticosteroid with a topical vitamin D analog would meet the requirement.
**b)** This topical corticosteroid was applied daily for at least 28 consecutive days; AND
**c)** Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescriber; AND
**ii.** Patients meets ALL of the following (a, b, and c):
**a)** Patient has tried at least one topical vitamin D analog; AND
Note: Examples of topical vitamin D analogs include calcipotriene cream, foam, ointment, solution (Dovonex, Vectical, generics), Sorilux. Concomitant use of a topical vitamin D analog with a topical corticosteroid would meet the requirement.
**b)** This topical vitamin D analog was applied daily for at least 28 consecutive days; AND
**c)** Inadequate efficacy was demonstrated with this topical calcineurin inhibitor, according to the prescriber.

**Initial Approval/ Extended Approval.**
**A)** *Initial Approval:* 1 year
**B)** *Extended Approval:* 1 year

Coverage of Zoryve 0.3% foam is recommended in those who meet the following criteria:

**3. Seborrheic Dermatitis**

Approve if the patient meets all of the following
**A)** Patient is ≥ 9 years of age; AND
**B)** Patient meets ALL the following criteria (a, b, and c):
- **i.** Patient has tried at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid; AND
  Note: Concomitant use of a topical corticosteroid in with a topical calcineurin inhibitor would meet the requirement.
- **ii.** This topical corticosteroid was applied daily for at least 28 consecutive days; AND
- **iii.** Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescriber.

**Initial Approval/ Extended Approval.**
**A)** *Initial Approval:* 1 year
**B)** *Extended Approval:* 1 year

Coverage of Opzelura cream is recommended in those who meet the following criteria:

**4. Vitiligo**
Approve if the patient meets all the following (A, B, C, D, E, and F):
**A)** Patient is ≥ 12 years of age; AND
**B)** Patient has nonsegmental vitiligo; AND
**C)** Patient has vitiligo involvement estimated to affect ≤ 10% of the body surface area; AND
**D)** Patient meets ONE of the following (i or ii):
- **i.** Patient meets ALL the following criteria (a, b, and c):
  - **a)** Patient has tried at least one high-, and/or super-high-potency prescription topical corticosteroid; AND
    Note: Concomitant use of a topical corticosteroid in with a topical calcineurin inhibitor would meet the requirement.
  - **b)** The duration of this topical corticosteroid therapy was at least 12 weeks; AND
    Note: Intermittent or continuous use of a topical corticosteroid for at least 12 weeks would meet the requirement.
  - **c)** Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescriber; OR
- **ii.** Patient is treating vitiligo affecting one of the following areas: face and/or skin folds; AND

**E)** Patients meets ALL the following (i, ii, and iii):
- **i.** Patient has tried at least one topical calcineurin inhibitor; AND
  Note: Examples of topical calcineurin inhibitors include tacrolimus ointment (Protopic, generic) and pimecrolimus cream (Elidel, generic). Concomitant use of a topical calcineurin inhibitor with a topical corticosteroid would meet the requirement.
- **ii.** This topical calcineurin inhibitor was applied daily for at least 12 weeks; AND
- **iii.** Inadequate efficacy was demonstrated with this topical calcineurin inhibitor, according to the prescriber; AND

**F)** The medication is prescribed by or in consultation with a dermatologist.

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**Initial Approval/ Extended Approval.**
**A)** *Initial Approval:* 1 year
**B)** *Extended Approval:* 1 year

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Topicals Agents for Atopic Dermatitis, Plaque Psoriasis, Seborrheic Dermatitis, and Vitiligo have not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Concurrent Use of Opzelura with a Biologic or with other JAK inhibitors.** Use of Opzelura in combination with therapeutic biologics or other JAK inhibitors is not recommended (see Appendix for examples).[1] Use of biologics or other JAK inhibitors was prohibited during the Opzelura pivotal studies.[2] There are no data evaluating combination use of Opzelura with these therapies; therefore, safety and efficacy of these combinations are unknown.

2. **Concurrent use of Opzelura with Other Potent Immunosuppressants** (e.g., azathioprine, cyclosporine). Use of Opzelura in combination with potent immunosuppressants is not recommended.[1] Use of systemic immunosuppressants was prohibited during the Opzelura pivotal studies.[2] There are no data evaluating combination of Opzelura with these therapies; therefore, safety and efficacy of these combinations are unknown.

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

**Documentation Requirements:**
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

## REFERENCES


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2. Protopic® ointment [prescribing information]. Madison, NJ: LEO; February 2019.
3. Eucrisa® ointment [prescribing information]. New York, NY: Pfizer; September 2025.
4. Triamcinolone acetonide cream [prescribing information]. Hawthorne, NY: Taro; July 2025.
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**Revised:**
11/20/2025: New Policy

**Reviewed:**
11/20/2025: Amanda R. Bolanz, PharmD, BCACP.

## APPENDIX

**Table 1. Examples of Other Therapeutic Biologics and Other JAK Inhibitors.**

| Product | Mechanism of Action |
|---|---|
| **Adalimumab SC Products** (Humira®, biosimilars) | Inhibition of TNF |
| **Cimzia®** (certolizumab pegol SC injection) | Inhibition of TNF |
| **Etanercept SC Products** (Enbrel®, biosimilars) | Inhibition of TNF |
| **Infliximab IV Products** (Remicade®, biosimilars) | Inhibition of TNF |
| **Simponi®, Simponi® Aria™** (golimumab SC injection; golimumab IV infusion) | Inhibition of TNF |
| **Zymfentra®** (infliximab-dyyb SC injection) | Inhibition of TNF |
| **Tocilizumab Products** (Actemra® IV, biosimilar; Actemra SC, biosimilar) | Inhibition of IL-6 |
| **Kevzara®** (sarilumab SC injection) | Inhibition of IL-6 |
| **Orencia®** (abatacept IV infusion, abatacept SC injection) | T-cell costimulation modulator |
| **Rituximab IV Products** (Rituxan®, biosimilars) | CD20-directed cytolytic antibody |
| **Kineret®** (anakinra SC injection) | Inhibition of IL-1 |
| **Ustekinumab Products** (Stelara® SC, biosimilars; Stelara IV, biosimilars) | Inhibition of IL-12/23 |
| **Siliq®** (brodalumab SC injection) | Inhibition of IL-17 |
| **Bimzelx®** (bimekizumab-bkzx SC injection) | Inhibition of IL-17A/17F |
| **Cosentyx®** (secukinumab IV infusion; secukinumab SC injection) | Inhibition of IL-17A |
| **Taltz®** (ixekizumab SC injection) | Inhibition of IL-17A |
| **Ilumya®** (tildrakizumab-asmn SC injection) | Inhibition of IL-23 |
| **Omvoh™** (mirikizumab-mrkz SC injection, mirikizumab IV injection) | Inhibition of IL-23 |
| **Skyrizi®** (risankizumab-rzaa SC injection; risankizumab-rzaa IV infusion) | Inhibition of IL-23 |
| **Tremfya®** (guselkumab SC injection; guselkumab IV infusion) | Inhibition of IL-23 |
| **Entyvio®** (vedolizumab IV infusion; vedolizumab SC injection) | Integrin receptor antagonist |
| **Otezla®** (apremilast tablets) | Inhibition of PDE4 |
| **Sotyktu™** (deucravacitinib tablets) | Inhibition of TYK2 |
| **Inrebic®** (fedratinib tablets) | Inhibition of JAK pathways |
| **Jakafi®** (ruxolitinib tablets) | Inhibition of JAK pathways |
| **Leqselvi™** (deuruxolitinib tablets) | Inhibition of JAK pathways |
| **Olumiant®** (baricitinib tablets) | Inhibition of JAK pathways |
| **Cibinqo®** (abrocitinib tablets) | Inhibition of JAK pathways |
| **Rinvoq®** (upadacitinib extended-release tablets) | Inhibition of JAK pathways |
| **Rinvoq® LQ** (upadacitinib oral solution) | Inhibition of JAKE pathways |
| **Xeljanz®** (tofacitinib tablets, oral solution) | Inhibition of JAK pathways |
| **Xeljanz® XR** (tofacitinib extended-release tablets) | Inhibition of JAK pathways |
| **Litfulo®** (ritlecitinib capsules) | Inhibition of kinases |
| **Xolair®** (omalizumab SC injection) | IgE antagonist |
| **Dupixent®** (dupilumab SC injection) | IL-4 receptor antagonist |
| **Cinqair®** (reslizumab IV injection) | IL-5 antagonist |
| **Nucala®** (mepolizumab SC injection) | IL-5 antagonist |
| **Fasenra®** (benralizumab SC injection) | IL-5 receptor antagonist |
| **Adbry®** (tralokinumab-ldrm SC injection) | IL-13 antagonist |
| **Ebglyss™** (lebrikizumab-lbkz SC injection) | IL-13 antagonist |
| **Nemluvio®** (nemlizumab-ilto SC injection) | IL-31 receptor antagonist |
| **Zeposia®** (ozanimod tablets) | Sphingosine 1 phosphate receptor modulator |
| **Velsipity®** (etrasimod tablets) | Sphingosine 1 phosphate receptor modulator |
| **Tezspire®** (tezepelumab-ekko SC injection) | TSLP blocker |

JAK – Janus kinase; SC – Subcutaneous; TNF – Tumor necrosis factor; IV – Intravenous; IL – Interleukin; PDE4 – Phosphodiesterase 4; TYK2 – Tyrosine kinase 2; IgE – Immunoglobulin E; TSLP – Thymic stromal lymphopoietin.