MEDICAL MUTUAL®

Drug Policy

Policy:	**Vtama and Zorvye Cream Preferred Step Therapy**	**Annual Review Date:** **01/16/2025**
Impacted Drugs:	**Vtama (tapnarof 1% cream – Dermavant)** **Zorvye (roflumilast 0.3% cream – Arcutis Biotherapetuics)**	**Last Revised Date:** **01/16/2025**

OVERVIEW

Vtama, an aryl hydrocarbon receptor agonist, is indicated for the topical treatment of **plaque psoriasis** in adults.[1] Zoryve, a phosphodiesterase 4 (PDE4) inhibitor, is indicated for the topical treatment of **plaque psoriasis**, including intertriginous areas, in patients ≥ 6 years of age.[2]

POLICY STATEMENT

This program has been developed to encourage the use of one or two Step 1 Product(s) prior to the use of a Step 2 Product. A trial of one Step 1a Product (Topical Corticosteroid) and one Step 1b Product (Topical Vitamin D Analog) is required prior to the use of a Step 2 Product; OR a trial of one Step 1c Product (Topical Corticosteroid/Topical Vitamin D Analog combination product) is required prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a history of one Step 1a and one Step 1b Product within the 130-day look-back period is excluded from Step Therapy. A patient with one Step 1c Product within the 130-day look-back period is also excluded from Step Therapy. This policy includes age edits: a patient < 6 years of age will be denied coverage for Zoryve and a patient < 18 years of age will be denied coverage for Vtama.

Step 1a: Topical Corticosteroids (medium-, medium-high, high-, and/or super-high potency prescription topical corticosteroid) [Brand and Generic Products] {See Table 1}

Table 1. Topical Corticosteroids (Groups 1, 2, 3, and 4).[5]

Generic Name	Strength	Formulations
Group 1: Super-High Potency		
Betamethasone dipropionate, augmented	0.05%	ointment, gel
Clobetasol propionate	0.05%	cream, foam, gel, lotion, ointment, shampoo
Diflorasone diacetate	0.05%	ointment
Fluocinonide	0.1%	cream
Flurandrenolide	4 mcg/m^2	tape
Halobetasol propionate	0.05%	cream, ointment, lotion
Group 2: High Potency		

Generic Name	Strength	Formulations
Amcinonide	0.1%	ointment
Betamethasone dipropionate, augmented	0.05%	cream, lotion
Betamethasone dipropionate	0.05%	cream, ointment
Desoximetasone	0.25%	cream, ointment, spray
	0.05%	gel
Fluocinonide	0.05%	cream, gel, ointment, solution
Halcinonide	0.1%	cream
Mometasone furoate	0.1%	ointment
Triamcinolone acetonide	0.5%	ointment
Group 3: Medium-High Potency		
Amcinonide	0.1%	cream, lotion
Betamethasone valerate	0.1%	ointment
Diflorasone diacetate	0.05%	cream
Fluocinonide-E	0.05%	cream
Fluticasone propionate	0.005%	ointment
Halcinonide	0.1%	ointment
Triamcinolone acetonide	0.5%	cream
Triamcinolone acetonide	0.1%	ointment
Group 4: Medium Potency		
Betamethasone valerate	0.12%	foam
Desoximetasone	0.05%	cream
Fluocinolone acetonide	0.025%	ointment
Flurandrenolide	0.05%	ointment
Hydrocortisone valerate	0.2%	ointment
Mometasone furoate	0.1%	cream, lotion, solution
Prednicarbate	0.1%	ointment

Step 1b: Topical Vitamin D Analogs: calcipotriene 0.005% cream (Dovonex, generic), calcipotriene 0.005% foam, calcipotriene 0.005% ointment, calcipotriene 0.005% solution, calcitriol 3 mcg/g ointment (Vectical, generic), Sorilux

Step 1c: calcipotriene 0.005% and betamethasone dipropionate 0.064% ointment (Taclonex, generic), calcipotriene 0.005% and betamethasone dipropionate 0.064% suspension (Taclonex, generic), Enstilar, Wynzora

Step 2: Vtama, Zoryve

PREFERRED STEP THERAPY CRITERIA

1. **Vtama.** Approve if the patient meets the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets one of the following (i, ii, or iii):
     - **i.** Patient has tried one Step 1a Product and one Step 1b product; OR
     - **ii.** Patient has tried one Step 1c Product.
     - **iii.** Patient is treating plaque psoriasis or atopic dermatitis affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia and has tried one Step 1b Product.

2. **Zoryve.** Approve if the patient meets the following (A and B):
   A) Patient is ≥ 6 years of age; AND
   B) Patient meets one of the following (i, ii, or iii):
      i. Patient has tried one Step 1a Product and one Step 1b product; OR
      ii. Patient has tried one Step 1c Product; OR
      iii. Patient is treating plaque psoriasis affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia and has tried one Step 1b Product.

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

Step Therapy Exception Criteria
Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

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

1. Vtama® topical cream [prescribing information]. Long Beach, CA: Dermavant; May 2022.
2. Zoryve™ cream [prescribing information.] Westlake, CA; Arcutis Biotherapeutics: October 2023.
3. Griffiths CEM, Armstrong AW, Gudjonsson JE, Barker JNWN. Psoriasis. *Lancet*. 2021;397:1301-1315.
4. Elmets C, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. *J Am Acad Dermatol*. 2021;84:432-470.
5. Facts and Comparisons® Online. Wolters Kluwer Health; 2021. Available at: https://fco.factsandcomparisons.com/lco/action/home. Accessed on October 09, 2023. Search terms: topical corticosteroids.