

## STEP THERAPY POLICY

- POLICY:** Topical Products – Vtama and Zoryve Step Therapy Policy
- Vtama® (tapinarof 1% cream – Dermavant)
  - Zoryve™ (roflumilast 0.3% cream – Arcutis Biotherapeutics)

**REVIEW DATE:** 11/16/2022

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### OVERVIEW

Vtama, an aryl hydrocarbon receptor agonist, is indicated for the topical treatment of **plaque psoriasis** in adults.<sup>1</sup> Zoryve, a phosphodiesterase 4 (PDE4) inhibitor, is indicated for the topical treatment of **plaque psoriasis**, including intertriginous areas, in patients  $\geq 12$  years of age.<sup>2</sup>

### Guidelines

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).<sup>3</sup> 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.<sup>4</sup> Neither Vtama nor Zoryve is 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 salicylic acid, and phototherapy.

### 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 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  $< 12$  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).<sup>5</sup>**

Generic Name	Strength	Formulations
<b>Group 1: Super-High Potency</b>		
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 <sup>2</sup>	tape
Halobetasol propionate	0.05%	cream, ointment, lotion
<b>Group 2: High Potency</b>		
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
<b>Group 3: Medium-High Potency</b>		
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
<b>Group 4: Medium Potency</b>		
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, Wyzora

**Step 2:** Vtama, Zoryve

## CRITERIA

1. **Vtama.** Approve if the patient meets the following criteria (A and B ):
  - A) Patient is  $\geq$  18 years of age; AND
  - B) Patient meets one of the following criteria (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 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 criteria (A and B ):
  - A) Patient is  $\geq$  12 years of age; AND
  - B) Patient meets one of the following criteria (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.
  
3. No other exceptions are recommended.

## REFERENCES

1. Vtama<sup>®</sup> topical cream [prescribing information]. Long Beach, CA: Dermavant; May 2022.
2. Zoryve<sup>™</sup> cream [prescribing information.] Westlake, CA; Arcutis Biotherapeutics: July 2022.
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<sup>®</sup> Online. Wolters Kluwer Health; 2021. Available at: <https://fco.factsandcomparisons.com/lco/action/home>. Accessed on November 11, 2022. Search terms: topical corticosteroids.