STEP THERAPY POLICY

POLICY: Topical Products – Vtama and Zoryve Cream Step Therapy Policy

• Vtama® (tapinarof 1% cream – Dermavant)

• Zorvve[™] (roflumilast 0.3% cream – Arcutis Biotherapeutics)

REVIEW DATE: 10/11/2023

OVERVIEW

Vtama, an aryl hydrocarbon receptor agonist, is indicated for the topical treatment of **plaque psoriasis** in adults.¹ Zoryve cream, a phosphodiesterase 4 (PDE4) inhibitor, is indicated for the topical treatment of **plaque psoriasis**, including intertriginous areas, in patients ≥ 6 years of age.² Of note, Zoryve is also available in a foam formulation for the treatment of seborrheic dermatitis in patients ≥ 9 years of age and is not included in this policy.

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).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 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.

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.

<u>Automation</u>: A patient with a of one Step 1a <u>and</u> 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 cream and a patient < 18 years of age will be denied coverage for Vtama.

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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

- **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 cream

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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 affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia and has tried one Step 1b Product.
- **2. Zoryve Cream.** Approve if the patient meets the following (A <u>and</u> 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 <u>and</u> has tried one Step 1b Product.
- 3. No other exceptions are recommended.

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.