Effective date: 12/1/2022 Last Reviewed: 9/2022, 6/2023, 5/2024, 2/2025 Scope: Medicaid

## VTAMA (tapinarof) cream

### POLICY

### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

- A. FDA-Approved Indications
  - 1. Plaque psoriasis in adults
  - 2. Atopic dermatitis in adults and pediatric patients 2 years of age and older

All other indications are considered experimental/investigational and not medically necessary.

## II. CRITERIA FOR INITIAL APPROVAL

### A. Plaque Psoriasis (PsO)

Initial authorization of 12 months may be granted for members when the following criteria are met:

- 1. Member is 18 years of age or older, diagnosed with plaque psoriasis
- 2. Documentation of affected area(s) and that the affected body surface area (BSA) is between 3-20%. Documentation of BSA affected is provided.
- 3. Vtama is prescribed by, or in consultation with, a specialist in dermatology or rheumatology.
- 4. Documentation that the member experienced an inadequate treatment response to at least a 2-4 consecutive week trial within the last 12 months of a high or super-high potency topical corticosteroid (e.g., augmented betamethasone, clobetasol). Contraindications, adverse effects and/or intolerance must be documented.
- 5. Documentation that the member experienced an inadequate treatment response or intolerance from two of the following therapies in combination with a topical corticosteroid within the last 12 months. Contraindications, adverse effects and/or intolerance must be documented.
  - a. Topical calcineurin inhibitors (e.g., tacrolimus ointment, pimecrolimus cream)
  - b. Topical vitamin D analogs (e.g., calcipotriene 0.005% ointment, cream, solution)
  - c. Topical retinoid (e.g., tazarotene cream 0.1%)
  - d. Phototherapy
  - e. Oral systemic non-biologic drugs (e.g., methotrexate, cyclosporine, or acitretin)
- 6. Documentation that the member experienced an inadequate treatment response or intolerance from Zoryve (roflumilast) cream 0.3% within the last 12 months. Contraindications, adverse effects and/or intolerance must be documented.
  - a. If the member is switching from a biologic for psoriasis treatment, they are not required to trial Zoryve before Vtama.
- 7. Vtama will not be used concomitantly with Zoryve (roflumilast) cream, any therapeutic biologic drug (e.g., adalimumab, infliximab), or any targeted synthetic drug (e.g., apremilast).

#### B. Atopic Dermatitis (AD)

Initial authorization of 12 months may be granted for members when the following criteria are met:



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- 1. Member is 2 years of age or older.
- 2. Vtama is prescribed by, or in consultation with, a specialist in dermatology or allergy/immunology.
- 3. Member has a diagnosis of AD. Documentation of BSA affected is provided.
- 4. Documentation that member experienced an inadequate treatment response or intolerance to at least one medium to super-high potency topical corticosteroid for at least 2 consecutive weeks. Contraindications, adverse effects and/or intolerance must be documented.
- 5. Documentation that member experienced an inadequate treatment response or intolerance to one of the following 3 formulary topical drugs: tacrolimus ointment for 6 consecutive weeks, pimecrolimus cream for 6 consecutive weeks and/or Eucrisa (crisaborole) ointment for 4 consecutive weeks. Contraindications, adverse effects and/or intolerance must be documented.
- 6. For members 6 years of age or older with mild to moderate disease, documentation that the member experienced an inadequate treatment response or intolerance from Zoryve (roflumilast) cream 0.15% within the last 12 months. Contraindications, adverse effects and/or intolerance must be documented.
  - a. If the member is switching from a biologic for AD treatment, they are not required to trial Zoryve before Vtama.
- 7. Vtama will not be used concomitantly with Eucrisa (crisaborole) ointment, Opzelura (ruxolitinib) cream, Zoryve (roflumilast) cream, any therapeutic biologic drug or any targeted synthetic drug

# **III. CONTINUATION OF THERAPY**

Authorization of 12 months may be granted for all members who are using the requested medication for plaque psoriasis and atopic dermatitis when the following criteria are met:

- 1. Documentation that member achieves or maintains a positive clinical response as evidenced by improvement in signs and symptoms of the condition when any of the following is met:
  - a. Reduction in body surface area (BSA) affected from baseline
  - b. Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain, clear or almost clear skin)
- 2. Vtama will not be used concomitantly with Zoryve (roflumilast) cream, Eucrisa (crisaborole) ointment, Opzelura (ruxolitinib) cream, any therapeutic biologic drug (e.g., adalimumab, infliximab) or any targeted synthetic drug (e.g., apremilast, upadacitinib).

## IV. QUANITY LIMIT

Vtama cream 1% has a quantity limit of 60 grams per 30 days.

## **V. REFERENCES**

1. Vtama (tapinarof) cream, for topical use. US FDA approved product information; Long Beach, CA: Dermavant Sciences, Inc; December 2024. Accessed January 2025.

