

Vtama[®] (tapinarof)

Policy # 00804

Original Effective Date: 09/12/2022

Current Effective Date: 01/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Select Calcipotriene Products are addressed separately in medical policy 00943.

Note: Zoryve[™] (roflumilast) is addressed separately in medical policy 00827.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Plaque Psoriasis

Based on review of available data, the Company may consider Vtama[®] (tapinarof) for the treatment of plaque psoriasis to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Vtama (tapinarof) for the treatment of plaque psoriasis will be considered when ALL of the following criteria are met:

- Patient has a diagnosis of plaque psoriasis; AND
- Patient is ≥ 18 years of age; AND
- Patient has psoriasis involvement estimated to affect $\leq 20\%$ of the body surface area; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient meets ONE of the following criteria:
 - Patient has tried at least TWO prescription topical corticosteroids of medium potency or higher (see policy guidelines) for at least 4 consecutive weeks EACH unless there is clinical evidence or patient history that suggests the use of topical corticosteroids will be ineffective or cause an adverse reaction to the patient; OR
 - Patient is treating psoriasis affecting one of the following areas: face, eyes/eyelids, skin fold, and/or genitalia; AND

*(Note: These specific patient selection criteria are additional Company requirements for coverage eligibility and will be denied as not medically necessary** if not met.)*

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- Patient has tried at least TWO topical vitamin D analogs (e.g., calcipotriene 0.005% solution, calcipotriene 0.005% cream, calcipotriene 0.005% ointment, calcitriol 3 mcg/g ointment, Enstilar [calcipotriene 0.005% and betamethasone dipropionate 0.064% foam]), for at least 4 consecutive weeks EACH unless there is clinical evidence or patient history that suggests the use of at least 2 topical vitamin D analogs will be ineffective or cause an adverse reaction to the patient.

*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

Atopic Dermatitis

Based on review of available data, the Company may consider Vtama (tapinarof) for the treatment of atopic dermatitis to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Vtama (tapinarof) for the treatment of atopic dermatitis will be considered when ALL of the following criteria are met:

- Patient has a diagnosis of atopic dermatitis; AND
- Patient is 2 years of age or older; AND
- Patient has 5% to 35% of their body surface area (BSA) impacted by atopic dermatitis; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient has tried and failed (e.g., intolerance or inadequate response) ONE prescription generic topical corticosteroid product unless there is clinical evidence or patient history that suggests the use of ONE prescription generic topical corticosteroid will be ineffective or cause an adverse reaction to the patient (e.g., atopic dermatitis lesions in sensitive areas such as the face or genital areas); AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient has tried and failed (e.g., intolerance or inadequate response) generic tacrolimus ointment OR generic pimecrolimus ointment unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.

*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Vtama (tapinarof) for the treatment of plaque psoriasis when the patient's psoriasis involvement affects greater than 20% of the body surface area to be **not medically necessary.****

Based on review of available data, the Company considers the use of Vtama (tapinarof) for the treatment of plaque psoriasis when the patient has not tried at least TWO topical corticosteroids for at least 4 consecutive weeks each (in the absence of psoriasis affecting a sensitive area) and when the patient has not tried at least TWO topical vitamin D analogs for at least 4 consecutive weeks each to be **not medically necessary.****

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Based on review of available data, the Company considers the use of Vtama (tapinarof) for the treatment of atopic dermatitis when the patient's atopic dermatitis involvement affects less than 5% OR greater than 35% of the body surface area to be **not medically necessary**.**

Based on review of available data, the Company considers the use of Vtama (tapinarof) for the treatment of atopic dermatitis when the patient has NOT tried and failed ONE prescription generic topical corticosteroid product AND either generic tacrolimus ointment or generic pimecrolimus ointment to be **not medically necessary**.**

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Vtama (tapinarof) when patient selection criteria are not met (except those denoted above as **not medically necessary****) to be **investigational**.*

Policy Guidelines

Topical Corticosteroid Potency

Medium Potency	High Potency	Super-high Potency
betamethasone valerate desoximetasone fluocinolone acetonide fluticasone propionate mometasone furoate triamcinolone acetonide 0.1% trianex triderm	amcinonide augmented betamethasone dipropionate cream apexicon E betamethasone dipropionate betamethasone valerate desoximetasone diflorasone diacetate fluocinonide fluocinonide E triamcinolone acetonide 0.5%	augmented betamethasone dipropionate ointment clobetasol emollient clobetasol propionate clodan cormax diflorasone diacetate halobetasol propionate

Background/Overview

Vtama is a 1% cream formulation of tapinarof, an aryl hydrocarbon receptor (AhR) agonist that is indicated for the topical treatment of plaque psoriasis in adults and for the topical treatment of atopic dermatitis in adults and pediatric patients 2 years of age and older. By modulating the AhR signaling pathway, this product regulates the skin barrier protein expression and normalization of skin cell differentiation. It should be administered topically to affected areas once daily.

There are various other treatment options for both plaque psoriasis and atopic dermatitis. First line agents for plaque psoriasis include topical corticosteroids and topical vitamin D analogs. Many of these agents are available in generic form. Treatment options for atopic dermatitis include first line agents such as topical corticosteroids (many of which are in generic form), and immunomodulating

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agents, such as generic tacrolimus and generic pimecrolimus. The availability of generic products in these treatment categories offer more economical options for the treatment of plaque psoriasis and atopic dermatitis versus the branded products available on the market. Additionally, there are no head-to-head studies comparing Vtama to any of the other products in these treatment categories to suggest superiority.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Vtama was approved in May 2022 for the topical treatment of plaque psoriasis in adults. In December 2024, Vtama was approved for the treatment of atopic dermatitis in adults and children 2 years of age and older.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Plaque Psoriasis

Two multicenter, randomized, double-blind, vehicle-controlled trials were conducted to evaluate the safety and efficacy of Vtama cream for the treatment of adults with plaque psoriasis (PSOARING 1 and PSOARING 2). These trials were conducted in a total of 1,025 subjects randomized 2:1 to Vtama cream or vehicle cream applied once daily for 12 weeks to any lesion regardless of anatomic location.

Baseline disease severity was graded using the 5-point Physician's Global Assessment (PGA). The majority of subjects had "moderate" disease (82%), while 10% had "mild" disease, and 8% had "severe" disease at baseline. The extent of disease involvement assessed by mean body surface area (BSA), excluding the scalp, palms, and soles, was 8% (range 3 to 20%). Subjects ranged in age from 18 to 75 years, with a median age of 51 years.

The primary efficacy endpoint in both studies was the proportion of subjects who achieved treatment success, defined as a PGA score of "clear" or "almost clear" and at least a 2-grade improvement from baseline at Week 12. In PSOARING 1, 36% of patients in the Vtama group achieved this endpoint compared to 6% of those in the placebo group which corresponds to a difference of 29% (95% CI: 22%, 36%). In PSOARING 2, 40% of the patients in the Vtama group met the primary endpoint compared to 6% in the placebo group. This corresponds to a difference of 34% (95% CI: 27%, 41%).

Atopic Dermatitis

Two multicenter, randomized, double-blind, vehicle-controlled trials were conducted to evaluate the safety and efficacy of Vtama cream for the treatment of adult and pediatric subjects 2 years of age

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and older with atopic dermatitis (ADORING 1 and ADORING 2). These trials were conducted in a total of 813 subjects (80% of subjects were 2 to 17 years of age) randomized 2:1 to Vtama cream or vehicle cream applied once daily for 8 weeks to any lesion regardless of anatomic location.

Baseline disease severity was graded using the 5-point validated Investigator's Global Assessment (vIGA-AD). The majority of subjects had "Moderate" disease (87%), while 13% had "Severe" disease at baseline. The extent of disease involvement assessed by mean affected BSA, excluding the scalp, was 16.8% (range 5 to 44%). The mean baseline Eczema Area and Severity Index (EASI) score was 12.9 (range 4.4 to 36.0). The mean baseline Peak Pruritus Numeric Rating Scale (PP-NRS) score for subjects 12 years of age and older was 6.4 on a scale of 0-10. Subjects ranged in age from 2 to 81 years, with a median age of 11 years.

The primary efficacy endpoint in both trials was the proportion of subjects who achieved treatment success, defined as a vIGA-AD score of "Clear" (0) or "Almost Clear" (1) and at least a 2-grade improvement from baseline. In ADORING 1, 45% of patients in the Vtama group achieved this endpoint compared to 14% of those in the placebo group which corresponds to a difference of 32% (95% CI: 23%, 40%). In ADORING 2, 46% of the patients in the Vtama group met the primary endpoint compared to 18% in the placebo group. This corresponds to a difference of 29% (95% CI: 19%, 38%).

References

1. Vtama [package insert]. Dermavant Sciences, Inc. Long Beach, CA. Updated December 2024.
2. Vtama Drug Evaluation. Express Scripts. Updated June 2022.

Policy History

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08/04/2022 Medical Policy Committee review

08/10/2022 Medical Policy Implementation Committee approval. New policy.

08/03/2023 Medical Policy Committee review

08/09/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged

08/01/2024 Medical Policy Committee review

08/14/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

07/03/2025 Medical Policy Committee review

07/09/2025 Medical Policy Implementation Committee approval. Added new FDA approved indication, atopic dermatitis, with relevant criteria and background information.

12/04/2025 Medical Policy Committee review

12/10/2025 Medical Policy Implementation Committee approval. Updated try/fail requirement to replace calcipotriene foam with calcipotriene solution.

Next Scheduled Review Date: 12/2026

***Investigational** – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.