Vtama® (tapinarof)

Policy # 00804
Original Effective Date: 09/12/2022
Current Effective Date: 09/09/2024

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.

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.*

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

Patient Selection Criteria

Coverage eligibility for Vtama (tapinarof) 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 ≤20% of the body surface area; AND
- 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 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% foam, 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.)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Vtama (tapinarof) 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.****

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.***

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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. 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 plaque psoriasis including first line agents such as topical corticosteroids and topical vitamin D analogs. Many of these agents are available in generic form which are often a more economical option for the treatment of plaque psoriasis compared to the available branded products. Additionally, there are no head to head studies comparing Vtama to any of the other products in this treatment category 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.

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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 federal regulations, other plan medical policies, and accredited national guidelines.

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 extend 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%).

References

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

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Policy History

Original Effective Date: 09/12/2022
Current Effective Date: 09/09/2024
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.
Next Scheduled Review Date: 08/2025

*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.

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**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.

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.