

## Select Calcipotriene Products

**Policy # 00943**

Original Effective Date: 01/01/2026

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: Zoryve™ (roflumilast) is addressed separately in medical policy 00827.*

*Note: Vtama® (tapinarof) is addressed separately in medical policy 00804.*

## 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 calcipotriene foam to be **eligible for coverage\*\*** when the patient selection criteria are met.

### Patient Selection Criteria

Coverage eligibility for calcipotriene foam will be considered when the following patient selection criteria are met:

- Patient has a diagnosis of plaque psoriasis of the scalp and body; AND
- Patient is 4 years of age or older; AND
- Patient has tried at least TWO medium-, medium-high-, high-, or super-high potency prescription topical corticosteroids 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's psoriasis affects the face, eyes/eyelids, skin folds, and/or genitalia making topical corticosteroid use impractical. Note that examples of medium-, medium-high-, high-, or super-high potency prescription topical corticosteroids include 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, and halobetasol propionate; 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)*

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- Patient has tried and failed at least TWO topical vitamin D analogs for at least 4 consecutive weeks EACH unless there is clinical evidence or patient history that suggests the use of at least 2 vitamin D analogs will be ineffective or cause an adverse reaction to the patient. Note that examples of topical vitamin D analogs include calcipotriene solution, cream, or ointment; calcitriol 3 mcg/g ointment; Enstilar<sup>®</sup>; calcipotriene 0.005% and betamethasone dipropionate 0.064% ointment or suspension.

*(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 calcipotriene foam when the patient has not failed the pre-requisite medications listed in the patient selection criteria 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 calcipotriene foam when the patient selection criteria have not been met (except those noted above as **not medically necessary**\*\*) to be **investigational**.\*

## Policy Guidelines

### Topical Corticosteroid Potency

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

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## **Background/Overview**

Calcipotriene is a synthetic vitamin D3 analog that has a similar receptor binding affinity to natural vitamin D3. However, the exact mechanism of action contributing to the clinical efficacy in the treatment of psoriasis is unknown.

### **Plaque Psoriasis**

Psoriasis is a common skin condition that is caused by an increase in production of skin cells. It is characterized by frequent episodes of redness, itching and thick, dry silvery scales on the skin. It is most commonly seen on the trunk, elbows, knees, scalp, skin folds and fingernails. This condition can appear suddenly or gradually and may affect people of any age; it most commonly begins between the ages of 15 and 35. Psoriasis is not contagious. It is an inherited disorder related to an inflammatory response in which the immune system produces too much tumor necrosis factor (TNF) alpha. It may be severe in immunosuppressed people or those who have other autoimmune disorders such as rheumatoid arthritis. First line agents for plaque psoriasis include topical corticosteroids and topical vitamin D analogs. Many of these agents are available in generic form. Additionally, the FDA has approved several steroid-free topical treatment options including Zoryve<sup>TM†</sup> (roflumilast) and Vtama<sup>®‡</sup> (tapinarof). Typical treatments for severe cases of plaque psoriasis include ultraviolet therapy or systemic therapies such as methotrexate or cyclosporine. Newer biologic therapies are also approved for the treatment of moderate to severe plaque psoriasis.

## **FDA or Other Governmental Regulatory Approval**

### **U.S. Food and Drug Administration (FDA)**

Calcipotriene foam was first approved by the FDA in 1993 under the brand name Sorilux<sup>TM‡</sup>. It is approved for the topical treatment of plaque psoriasis of the scalp and body in adults and pediatric patients 4 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.

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests a prescription generic topical corticosteroid or topical vitamin D analog will be ineffective or cause an adverse reaction to the patient. Based on review of this data, in the absence of the above mentioned caveats, there is no advantage of using calcipotriene foam prior to topical corticosteroids or topical vitamin D analogs for the treatment of plaque psoriasis of the scalp and body.

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## **References**

1. Sorilux (calcipotriene foam). [package insert]. Mayne Pharma. Raleigh, NC. Updated May 2024.

## **Policy History**

Original Effective Date: 01/01/2026

Current Effective Date: 01/01/2026

10/02/2025 Medical Policy Committee review

10/08/2025 Medical Policy Implementation Committee approval. New policy.

Next Scheduled Review Date: 10/2026

\*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.

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‡ 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.