LOUISIANA BLUE

Zoryve™ (roflumilast)

Policy # 00827
Original Effective Date: 02/13/2023
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: 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 Zoryve™‡ (roflumilast cream and roflumilast foam) to be **eligible for coverage**** when the patient selection criteria are met.

Zoryve cream

Patient Selection Criteria

Coverage eligibility for Zoryve (roflumilast cream) will be considered when the following patient selection criteria are met for the requested drug:

- Requested drug is **Zoryve 0.05% cream**:
  - Patient has a diagnosis of mild to moderate atopic dermatitis; AND
  - Patient is 2 to 5 years of age; AND
  - 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)*

- Requested drug is **Zoryve 0.15 % cream**:
  - Patient has a diagnosis of mild to moderate atopic dermatitis; AND
  - Patient is 6 years of age or older; AND
  - 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)*
- Requested drug is **Zoryve 0.3 % cream**:
  - Patient has a diagnosis of plaque psoriasis; AND
  - Patient is 6 years of age or older; AND
  - Patient's psoriasis affects less than or equal to 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.)*
  - Zoryve will not be used in combination with Otezla®‡ (apremilast); 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.)*

- 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 0.005% solution, cream, or ointment; calcitriol 3 mcg/g ointment; Enstilar; 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.)*

Zoryve foam

Patient Selection Criteria

Coverage eligibility for Zoryve (roflumilast foam) will be considered when the following patient selection criteria are met for the requested drug:

- Requested drug is **Zoryve foam**:
  - Patient meets ONE of the following:
    - Patient has a diagnosis of seborrheic dermatitis; AND
      - Patient is 9 years of age or older; AND
      - Patient has tried and failed (e.g., intolerance or inadequate response) at least TWO of the following generic prescription topical antifungal products for seborrheic dermatitis: ketoconazole foam, ciclopirox gel, ciclopirox shampoo 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; 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) at least TWO generic formulary low potency topical corticosteroids. Note that examples of generic formulary low potency topical corticosteroids include fluocinolone 0.01% body oil, fluocinolone 0.01% scalp oil, desonide 0.05% cream, desonide 0.05% ointment, desonide 0.05% lotion, hydrocortisone 2.5% cream, hydrocortisone 2.5% ointment, and hydrocortisone 2.5% lotion; **OR**
        *(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 a diagnosis of plaque psoriasis of the scalp and body; AND
      - Patient is 12 years of age or older; AND
      - Patient's psoriasis affects less than or equal to 25% of the body surface area; AND

- Zoryve will not be used in combination with Otezla (apremilast); 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.)*
- 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 0.005% solution, cream, or ointment; calcitriol 3 mcg/g ointment; Enstilar; 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 Zoryve 0.05% cream (roflumilast 0.05% cream) or Zoryve 0.15% (roflumilast 0.15% cream) 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.****

Based on review of available data, the Company considers the use of Zoryve 0.3% (roflumilast 0.3% cream) or Zoryve foam (roflumilast foam) for the treatment of plaque psoriasis when the patient's psoriasis affects greater than 20% of the body surface area or the patient has not tried at least TWO topical corticosteroids and TWO topical vitamin D analogs to be **not medically necessary.****

Based on review of available data, the Company considers the use of Zoryve foam (roflumilast foam) for the treatment of seborrheic dermatitis 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 Zoryve (roflumilast cream and roflumilast 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 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

Zoryve is a topical phosphodiesterase 4 (PDE4) inhibitor. Zoryve is available as a 0.05 % cream, a 0.15% cream, a 0.3% cream and a 0.3% foam. The 0.05% and 0.15% cream formulations are indicated for the topical treatment of mild to moderate atopic dermatitis and are differentiated by the age group for which they're approved. The 0.05% cream is approved in pediatric patients 2 to 5 years of age, and the 0.15% cream is approved in adult and pediatric patients 6 years of age and older. Zoryve 0.05% and 0.15% cream should be applied to the affected areas once daily. Several treatment options for atopic dermatitis exist including first line agents, such as topical corticosteroids (many of which are in generic form) and immunomodulating agents, such as generic tacrolimus and generic pimecrolimus. The availability of generic products in this treatment category lends itself to

be a more cost-effective option for the treatment of atopic dermatitis versus the branded products available on the market. To note, there are no head-to-head studies with Zoryve versus the other products in this treatment category to suggest superiority.

Zoryve 0.3% cream is indicated for the treatment of plaque psoriasis, including intertriginous areas. It is thought to work by decreasing the production of immune modulators contributing to the condition. It should be applied to the affected areas once daily. Zoryve is the only topical therapy specifically FDA-approved for the treatment of intertriginous psoriasis. However, other topical products can be used to treat psoriasis in these areas and the efficacy of Zoryve in the treatment of intertriginous psoriasis has not been extensively studied. Zoryve 0.3% foam is approved for the treatment of plaque psoriasis of the scalp and body in adult and pediatric patients 12 years of age and older. For this indication, Zoryve foam should be applied to the 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 Zoryve to any of the other products in this treatment category to suggest superiority.

Zoryve 0.3% foam is also indicated for the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older. The specific mechanisms by which Zoryve foam exerts its therapeutic action in seborrheic dermatitis are not well defined. Zoryve foam is applied once daily to affected areas on the skin or scalp when dry.

Therapies for seborrheic dermatitis include antifungals, keratolytics, antipruritics, and anti-inflammatories which are available in various formulations such as creams, gels, shampoos, and foams. The treatment formulation of choice is generally guided by patient specific factors. Commonly used topical treatments for scalp and non-scalp seborrheic dermatitis consist of ciclopirox, ketoconazole, hydrocortisone, salicylic acid, and tacrolimus. Zoryve foam has not been studied in comparison to other therapies used for seborrheic dermatitis and is considered an alternative to other topical therapies in this treatment category.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Zoryve 0.3% cream was approved in July 2022 for the topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older. In October 2023, the FDA expanded the approval of Zoryve 0.3% cream for the topical treatment of plaque psoriasis, including intertriginous areas, to include patients 6 years of age and older. Zoryve foam was approved by the FDA for the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older in December 2023. In July 2024, the FDA approved Zoryve 0.15% cream for the topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older. In May 2025, Zoryve foam was approved by the FDA for the treatment of plaque psoriasis of

the scalp and body in adult and pediatric patients 12 years of age and older. A new strength of Zoryve cream, 0.05%, was approved in October 2025 for the topical treatment of mild to moderate atopic dermatitis in pediatric patients 2 to 5 years of age.

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.

Atopic Dermatitis

The efficacy of Zoryve 0.15% cream was evaluated in two multicenter, randomized, double-blind, vehicle-controlled trials (INTEGUMENT-1 and INTEGUMENT-2). A total of 1337 adult and pediatric subjects 6 years of age and older (615 subjects were 6 to 17 years of age) with mild to moderate atopic dermatitis were enrolled. Subjects were randomized 2:1 to receive Zoryve cream, 0.15%, or vehicle cream applied once daily for 4 weeks. The median age of the trial population was 20 years (range 6 to 91 years of age). At baseline, subjects had a mean affected BSA of 14% (range of 3% to 88%), and 42% had facial involvement. At baseline, 24% of subjects had a validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) score of 2 (mild), and 76% had a vIGA-AD score of 3 (moderate). Eight hundred thirteen (60.8%) subjects 12 years of age and older had a baseline WI-NRS score of 4 or higher on a scale of 0 to 10. The primary endpoint was the proportion of subjects who achieved vIGA-AD treatment success at Week 4. Success was defined as a score of "Clear" (0) or "Almost Clear" (1), plus a 2-grade improvement from baseline. In INTEGUMENT-1, 32% of patients achieved the primary outcome of vIGA-AD success in the Zoryve treated group compared to 15.2% in the vehicle treated group ($P < 0.0001$). In INTEGUMENT-2, 28.9% of patients achieved the primary outcome of vIGA-AD success in the Zoryve treated group compared to 12% in the vehicle treated group ($P < 0.0001$).

A multicenter, randomized, double-blind, vehicle-controlled trial (INTEGUMENT-PED) enrolled a total of 652 pediatric subjects 2 to 5 years of age with mild to moderate atopic dermatitis. Subjects were randomized 2:1 to receive Zoryve cream, 0.05%, or vehicle cream applied once daily for 4 weeks. The median age of the trial population was 3 years (range 2 to 5 years of age). At baseline, subjects had a mean affected BSA of 22% (range of 3% to 82%), and 53% had facial involvement. At baseline, 22% of subjects had a validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) score of 2 (mild), and 78% had a vIGA-AD score of 3 (moderate). The primary endpoint was the proportion of subjects who achieved vIGA-AD treatment success at Week 4. Success was defined as a score of "Clear" (0) or "Almost Clear" (1), plus a 2-grade improvement from baseline. In INTEGUMENT-PED, 25.4% of patients achieved the primary outcome of vIGA-AD success in the Zoryve treated group compared to 10.7% in the vehicle treated group ($P < 0.0001$).

Plaque Psoriasis
The efficacy of Zoryve 0.3% cream was established in two multicenter, randomized, double-blind, vehicle-controlled trials (DERMIS-1 and DERMIS-2). Both trials enrolled a total of 881 subjects with mild to severe plaque psoriasis and an affected BSA of 2% to 20%. The study population ranged in age from 6 to 88 years with 4 subjects younger than 12 years of age at baseline. At baseline, 16% of subjects had an Investigator's Global Assessment (IGA) score of 2 (mild), 76% had an IGA score of 3 (moderate), and 8% had an IGA score of 4 (severe). One hundred seventy nine (20%) patients had an intertriginous IGA (I-IGA) score of 2 or higher, and 678 (77%) had a baseline Worst Itch-Numeric Rating Score (WI-NRS) score of 4 or higher on a scale of 0 to 10. Subjects were randomized 2:1 To receive Zoryve or vehicle applied once daily for 8 weeks. The primary endpoint was the proportion of subjects who achieved IGA treatment success at Week 8. Success was defined as a score of "Clear" (0) or "Almost clear" (1), plus a 2-grade improvement from baseline. In DERMIS-1, 41.5% of patients achieved IGA success in the Zoryve group compared to 5.8% in the vehicle group. In DERMIS-2, 36.7% of patients achieved IGA success compared to 7.1% in the vehicle group.

The efficacy of Zoryve foam was evaluated in two randomized, double-blind, vehicle-controlled trials, ARRECTOR and Trial 204, which enrolled a total of 736 adult and pediatric subjects 12 years of age and older with mild to severe plaque psoriasis of the scalp and body. In each trial, subjects were randomized 2:1 to receive Zoryve foam, 0.3%, or vehicle foam applied once daily for 8 weeks. The median age was 47 years (range 12 to 87 years). In Trial ARRECTOR, the trial population ranged in age from 12 to 87 years, including 2% of subjects who were 12 to 17 years of age and 13% of subjects who were 65 years of age or older. At baseline, 86% of subjects had a Scalp Investigator Global Assessment (S-IGA) score of 3 (moderate) on a 5-point scale of 0 to 4, and 14% had an S-IGA score of 4 (severe); 28% of subjects had a Body Investigator Global Assessment (B-IGA) score of 2 (mild), 67% of subjects had a B-IGA score of 3 (moderate), and 5% had a B-IGA score of 4 (severe). At baseline, 76% of subjects had a Scalp Itch-Numeric Rating Scale (SI-NRS) score of 4 or higher on a scale of 0 to 10 and 73% had a Worst Itch-Numeric Rating Scale (WI-NRS) score of 4 or higher. In Trial 204, the trial population ranged in age from 12 to 87 years, including 1% of subjects who were 12 to 17 years of age, and 9% who were 65 years of age or older. At baseline, 11% of subjects had an S-IGA score of 2 (mild), 76% of subjects had an S-IGA score of 3 (moderate), and 13% had an S-IGA score of 4 (severe); 36% of subjects had a B-IGA score of 2 (mild), 59% of subjects had a B-IGA score of 3 (moderate), and 5% had a B-IGA score of 4 (severe). At baseline, 89% of subjects had an SI-NRS score of 4 or higher on a scale of 0 to 10. In both trials, S-IGA treatment success, a primary endpoint in ARRECTOR and Trial 204, and B-IGA treatment success, a primary endpoint in ARRECTOR, were defined as a score of "Clear" or "Almost Clear" (1), plus a 2-grade improvement from baseline. SI-NRS success and WI-NRS success were defined as a reduction of at least 4 points from baseline with a baseline score of at least 4. In Trial ARRECTOR, among subjects with a baseline SI-NRS score of at least 4 (75% of subjects), a higher percentage of subjects achieved SI-NRS success at Week 8 in the group who received Zoryve foam, 0.3%, compared to the group who received vehicle foam (65.3% vs. 30.3% for a treatment difference of 35.4% and 95% CI of [23.9,47.0]). In Trial ARRECTOR, among subjects with a baseline WI-NRS

score of at least 4 (72% of subjects), a higher percentage of subjects achieved WI-NRS success at Week 8 in the group who received Zoryve foam, 0.3%, compared to the group who received vehicle foam (63.1% vs. 30.1% for a treatment difference of 32.8% and 95% CI of [20.3, 45.2]).

Seborrheic Dermatitis
The efficacy of Zoryve foam was evaluated in two randomized, double-blind, vehicle-controlled, multicenter, pivotal studies in patients with moderate or severe seborrheic dermatitis affecting the scalp and/or non-scalp areas. The affected body surface area was around 3%. STRATUM, a Phase III trial, included adults and pediatric patients > 9 years of age while Trial 203, a Phase IIa study, involved patients > 18 years of age. The primary efficacy endpoint for each was the proportion of patients that achieved Investigator Global Assessment (IGA) treatment success, defined as an IGA score of 0 (clear) or 1 (almost clear) with > 2-grade improvement from baseline at Week 8. An IGA is a five-point scale that provides a global clinical assessment of seborrheic dermatitis severity ranging from 0 to 4, where scores > 3 denote moderate or severe seborrheic dermatitis. Secondary endpoints included the proportion of patients who achieved an IGA score of 0 at Week 8, Worst Itch-Numeric Rating Scale (WI-NRS) success sequentially at Weeks 2, 4, and 8, and erythema and scaling scores of 0 at Week 8. Patients were randomized (2:1) to Zoryve 0.3% foam or vehicle foam which was applied once daily for 8 weeks. Of the 475 participants enrolled in STRATUM, 79.5% of patients treated with Zoryve foam achieved IGA treatment success at Week 8 compared with 58.0% of patients given vehicle foam ($P < 0.0001$). Among those with a baseline WI-NRS score of at least 4 (67% of patients), a larger percentage of patients had a reduction of at least 4 points from baseline in the Zoryve foam group (62.8%) compared with the group given vehicle foam (40.6%). A significantly greater proportion of patients treated with Zoryve foam demonstrated improvements in other secondary endpoints compared with vehicle foam ($P < 0.0001$). In Trial 203, which enrolled 226 patients, at Week 8, 73.8% of patients treated with Zoryve foam achieved IGA treatment success compared with 40.9% of patients given vehicle foam ($P < 0.001$). A significantly greater proportion of patients treated with Zoryve foam demonstrated improvements in all secondary endpoints compared with vehicle foam ($P < 0.001$).

References

1. Zoryve cream [package insert]. Arcutis Biotherapeutics, Inc. Westlake Village, CA. Updated October 2025.
2. Zoryve Drug Evaluation. Express Scripts. Updated August 2022.
3. Zoryve foam [package insert]. Arcutis Biotherapeutics, Inc. Westlake Village, CA. May 2025.
4. Zoryve Foam Drug Evaluation. Express Scripts. January 2024.

Policy History

Original Effective Date: 02/13/2023
Current Effective Date: 01/01/2026
01/05/2023 Medical Policy Committee review
01/11/2023 Medical Policy Implementation Committee approval. New policy.
04/04/2024 Medical Policy Committee review

04/10/2024	Medical Policy Implementation Committee approval. Updated the age requirement for Zoryve cream to 6 years of age (previously 12 years of age) per the updated FDA package insert. Added new formulation, Zoryve foam with relevant criteria and background information. Removed "cream" from title.
12/05/2024	Medical Policy Committee review
12/11/2024	Medical Policy Implementation Committee approval. Added new strength, Zoryve 0.15% cream, with relevant criteria and background information.
12/04/2025	Medical Policy Committee review
12/10/2025	Medical Policy Implementation Committee approval. Added new strength, Zoryve 0.05% cream, with relevant criteria and background information. Added new FDA approved indication for Zoryve foam, plaque psoriasis, with criteria. Updated relevant background and rationale information. Updated try/fail requirement for Zoryve 0.3% cream to replace calcipotriene foam with calcipotriene solution. Added policy guidelines section to the policy.

*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.

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.