Effective Date **4/15/2024**
Coverage Policy Number **IP0527**

Roflumilast

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for roflumilast 0.3% cream, 0.3% topical foam (**Zoryve**™).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Initial Approval Criteria

Roflumilast 0.3% cream (Zoryve) is considered medically necessary for the treatment of Plaque Psoriasis when the individual meets ALL of the following criteria:

1. 6 years of age or older
2. Psoriasis involvement estimated to affect no more than 20% of the body surface area
3. **ONE** of the following:
    a. Documented inadequate response, contraindication or intolerance to **ONE** prescription topical corticosteroid, medium potency or higher [see Appendix 1 for examples], taken for at least 28 days

b. Individual is treating psoriasis affecting one of the following areas: face, skin folds, and/or genitalia
4. Documented inadequate response, contraindication or intolerance to **ONE** topical vitamin D analog applied daily for at least 2 consecutive weeks (for example, calcipotriene, calcitriol)
5. Medication is prescribed by or in consultation with, a dermatologist

Concomitant use of a topical corticosteroid and a topical vitamin D analog would meet requirements [3] and [4].

Roflumilast 0.3% topical foam (Zoryve) is considered medically necessary for the treatment of Seborrheic Dermatitis when the individual meets ALL of the following criteria:

1. 9 years of age or older
2. **ONE** of the following:
    a. Documented failure, contraindication or intolerance to ONE of the following:
        a. Topical ketoconazole
        b. Topical ciclopirox
    b. Is 9 year to 12 years of age

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Continuation of Therapy

Continuation of Roflumilast (Zoryve) is considered medically necessary for **ALL** covered diagnoses when initial criteria are met AND beneficial response is demonstrated.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

OVERVIEW
Zoryve, a phosphodiesterase 4 (PDE4) inhibitor, is indicated for the topical treatment of **plaque psoriasis**, including intertriginous areas, in patients ≥ 6 years of age.[1] The pivotal studies enrolled patients with plaque psoriasis, with a body surface area involvement of 2% to 20%. **Zoryve foam is indicated for the treatment of seborrheic dermatitis in adult and pediatric patients ≥ 9 years of age.**

Otezla (apremilast tablets), an oral PDE4 inhibitor, is indicated for the treatment of patients with moderate to severe plaque psoriasis who are not candidates for phototherapy or systemic therapy.[2] Otezla is also indicated for the treatment of psoriatic arthritis and oral ulcers associated with Behçet's disease. Concomitant use of two products with the same mechanism of action is generally not recommended.

Guidelines

The mainstay of treatment of plaque psoriasis is topical therapy, including corticosteroids, vitamin D analogs, calcineurin inhibitors, keratolytics (e.g., tazarotene), and combination therapies (e.g., a corticosteroid with a vitamin D analog).[3] Joint guidelines from the American Academy of Dermatology (AAD) and the Medical Board of the National Psoriasis Foundation (NPF) [2021] have been published for the management of psoriasis with topical therapies.[4] Zoryve is not yet addressed in the guidelines. Use of a topical corticosteroid for up to 4 weeks is recommended for plaque psoriasis not involving intertriginous areas (strength of recommendation, A). A topical vitamin D analog can be used long-term (up to 52 weeks) for the treatment of psoriasis (strength of recommendation, A). Guidelines also address use of topical calcineurin inhibitors, topical tazarotene, topical salicyclic acid, and phototherapy.

Additional Clinical Information
Appendix 1
Topical Corticosteroids, Classified According to Potency (Adapted from Facts/Comparisons).[5]

Potency/Group	Examples
Super-high potency (Group 1)	augmented betamethasone dipropionate 0.05% gel, lotion, ointment; clobetasol propionate 0.05% cream, cream (emollient base), foam aerosol, gel, lotion, ointment, shampoo, solution (scalp), spray aerosol; fluocinonide 0.1% cream; flurandrenolide 4 mcg/cm^2 tape; halobetasol propionate 0.05% cream, lotion, ointment.
High potency (Group 2)	amcinonide 0.1% ointment; betamethasone dipropionate 0.05% cream (augmented), ointment; clobetasol propionate 0.025% cream; desoximetasone 0.25% cream, ointment, spray; desoximetasone 0.05% gel; diflorasone diacetate 0.05% cream (emollient), ointment; fluocinonide 0.05% cream, gel, ointment, solution; halcinonide 0.1% cream, ointment; halobetasol propionate 0.01% lotion.
Medium-High potency (Group 3)	amcinonide 0.1% cream, lotion; betamethasone dipropionate 0.05% cream (hydrophilic emollient); betamethasone valerate 0.1% ointment; betamethasone valerate 0.12% foam; desoximetasone 0.05% cream; diflorasone diacetate 0.05% cream; fluocinonide 0.05% cream (aqueous emollient); fluticasone propionate 0.005% ointment; mometasone furoate 0.1% ointment; triamcinolone acetonide 0.5% cream, ointment.
Medium potency (Group 4)	betamethasone propionate 0.05% spray; clocortolone pivalate 0.1% cream; fluocinolone acetonide 0.025% ointment; flurandrenolide 0.05% ointment; hydrocortisone valerate 0.2% ointment; mometasone furoate 0.1% cream, lotion, ointment, solution; triamcinolone acetonide 0.1% cream, ointment; triamcinolone acetonide 0.05% ointment; triamcinolone acetonide 0.2 mg aerosol spray.
Lower-mid potency (Group 5)	betamethasone dipropionate 0.05% lotion; betamethasone valerate 0.1% cream; desonide 0.05% gel, ointment; fluocinolone acetonide 0.025% cream; flurandrenolide 0.05% cream, lotion; fluticasone propionate 0.05% cream, lotion; hydrocortisone butyrate 0.1% cream, lotion, ointment, solution; hydrocortisone probutate 0.1% cream; hydrocortisone valerate 0.2% cream; prednicarbate 0.1% cream (emollient), ointment; triamcinolone acetonide 0.1% lotion; triamcinolone acetonide 0.025% ointment.
Low potency (Group 6)	aclometasone dipropionate 0.05% cream, ointment; betamethasone valerate 0.1% lotion; desonide 0.05% cream, foam, lotion; fluocinolone acetonide 0.01% cream, oil, shampoo, solution; triamcinolone acetonide 0.025% cream, lotion.
Least potent	hydrocortisone 2.5% cream, ointment, solution; hydrocortisone 2% lotion; hydrocortisone 1% cream, gel, lotion, ointment, solution, spray; hydrocortisone

(Group 7)	0.5% cream, ointment; hydrocortisone acetate 2.5% cream; hydrocortisone acetate 2% lotion.

References

1. Zoryve™ cream [prescribing information.] Westlake, CA; Arcutis Biotherapeutics: October 2023.
2. Otezla® tablets [prescribing information]. Summit, NJ; Celgene; December 2021.
3. Griffiths CEM, Armstrong AW, Gudjonsson JE, Barker JNWN. Psoriasis. Lancet. 2021; 397:1301-1315.
4. Elmets C, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol. 2021; 84:432-470.

Supplemental References

5. Facts and Comparisons Online. Wolters Kluwer Health, Inc.; 2022. Available at: http://online.factsandcomparisons.com/login.aspx?url=/index.aspx&qs=. Accessed on May 9, 2022. Search terms: doxepin, corticosteroid.