Cigna National Formulary Coverage Policy

Prior Authorization
Dermatology – Zoryve™ (roflumilast 0.3% cream)

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INTRODUCTIO N
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.

National Formulary Medical Necessity

Cigna covers roflumilast 0.3% cream (Zoryve™) as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:

Prior Authorization is recommended for prescription benefit coverage of Zoryve. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of individuals treated with Zoryve as well as the monitoring required for adverse events, approval requires Zoryve to be prescribed by or in consultation with a physician who specializes in the condition being treated.

FDA Indication(s)

1. Plaque Psoriasis. Approve for 1 year if the individual meets ALL of the following criteria (A, B, C, D, E, and F):
   A) Individual is ≥ 12 years of age; AND
   B) Individual has psoriasis involvement estimated to affect ≤ 20% of the body surface area; AND
   C) Individual is not receiving concomitant treatment with Otezla® (apremilast tablets); AND
   D) Individual meets one of the following criteria (i or ii):

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i. Individual meets all of the following criteria (a, b, and c):
   a) Individual has tried at least one medium-, medium-high, high-, and/or super-high potency
      prescription topical corticosteroid; AND
   b) This topical corticosteroid was applied daily for at least 4 consecutive weeks; AND
   c) Inadequate efficacy was demonstrated with this topical corticosteroid, according to the
      prescriber; OR

ii. Individual is treating psoriasis affecting one of the following areas: face, eyes/eyelids, skin folds,
    and/or genitalia; AND

E) Individual meets ALL of the following criteria (i, ii, and iii):
   i. Individual has tried at least one topical vitamin D analog; AND
      Note: Examples of topical vitamin D analogs include calcipotriene 0.005% foam (Sorilux, authorized
      generic), calcipotriene 0.005% cream (Dovonex, generic), calcipotriene 0.005% ointment (generic
      only), calcitriol 3 mcg/g ointment (Vectical, generic), calcipotriene 0.005% and betamethasone
dipropionate 0.064% foam (Enstilar), calcipotriene 0.005% and betamethasone dipropionate 0.064% cream
      (Wynzora), calcipotriene 0.005% and betamethasone dipropionate 0.064% ointment
      (Taclonex, generic), calcipotriene 0.005% and betamethasone dipropionate 0.064% suspension
      (Taclonex, generic). Concomitant use of a topical vitamin d analog and a topical corticosteroid
      would meet the requirement.
   ii. This topical vitamin D analog was applied daily for at least 4 consecutive weeks; AND
   iii. Inadequate efficacy was demonstrated with this topical vitamin D analog, according to the
      prescriber; AND

F) The medication is prescribed by or in consultation with a dermatologist.

Conditions Not Covered
Roflumilast (Zoryve™) is considered experimental, investigational or unproven for ANY other use.

Background
Overview
Zoryve, a phosphodiesterase 4 (PDE4) inhibitor, is indicated for the topical treatment of plaque psoriasis,
including intertriginous areas, in patients ≥ 12 years of age.¹ The pivotal studies enrolled patients with plaque
psoriasis, with a body surface area involvement of 2% to 20%.

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
salicylic acid, and phototherapy.

References
1. Zoryve™ cream [prescribing information.] Westlake, CA; Arcutis Biotherapeutics: July 2022.
2. Otezla® tablets [prescribing information]. Summit, NJ; Celgene; December 2021.

## Revision History

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<thead>
<tr>
<th>Type of Revision</th>
<th>Summary of Changes</th>
<th>Approval Date</th>
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<tbody>
<tr>
<td>New Policy</td>
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<td>08/10/2022</td>
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