Effective date: 12/1/2022
Last Reviewed: 9/2022, 6/2023
Scope: Medicaid

ZORYVE (roflumilast) cream

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
ZORYVE is a phosphodiesterase 4 inhibitor indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. Initial requests:
1. Chart notes or medical record documentation of affected area(s) and percentage of body surface area (BSA) affected.
2. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

B. Continuation requests:
1. Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

III. CRITERIA FOR INITIAL APPROVAL

Plaque Psoriasis (PsO)

Initial authorization of 12 months may be granted for members when the following criteria are met:

1. Member is 12 years of age or older, diagnosed with plaque psoriasis
2. BSA affected is between 2-20%. Documentation of BSA affected is provided.
3. Zoryve is prescribed by, or in consultation with, a specialist in dermatology or rheumatology.
4. Member experienced an inadequate treatment response to at least a 2-4 consecutive week trial within the last 12 months of a high or ultra-high potency topical corticosteroid (e.g., augmented betamethasone, clobetasol). Contraindications, adverse effects and/or intolerance must be documented.
5. Member experienced an inadequate treatment response or intolerance from two of the following therapies in combination with a topical corticosteroid within the last 12 months. Contraindications, adverse effects and/or intolerance must be documented.
    a. Topical calcineurin inhibitors (e.g., tacrolimus ointment, pimecrolimus cream)
    b. Topical vitamin D analogs (e.g., calcipotriene 0.005% ointment, cream, solution)
    c. Topical retinoid (e.g., tazarotene cream 0.1%)
    d. Phototherapy
    e. Oral systemic non-biologic drugs (e.g., methotrexate or cyclosporine)

6. Zoryve will not be used concomitantly with Vtama (tapinoraf) cream, any biologic DMARD (e.g., adalimumab, infliximab) or any targeted synthetic DMARD (e.g., apremilast).

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for all members who are using the requested medication for plaque psoriasis psoriasis when the following criteria are met:

1. Member achieves or maintains a positive clinical response as evidenced by improvement in signs and symptoms of the condition when any of the following is met:
    a. Reduction in body surface area (BSA) affected from baseline
    b. Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)
2. Zoryve will not be used concomitantly with Vtama (tapinoraf) cream, any biologic DMARD (e.g., adalimumab, infliximab) or any targeted synthetic DMARD (e.g., apremilast).

V. QUANITY LIMIT

1. 60 grams per 30 days

VI. REFERENCES

1. Zoryve (roflumilast) cream, for topical use. US FDA approved product information; Westlake Village, CA: Arcutis Biotherapeutics, Inc; July 2022. https://www.arcutis.com/wp-content/uploads/USPI-roflumilast-cream-FDAapproved-V1-29Jul2022.pdf (Accessed on September 6, 2022).