STEP THERAPY POLICY

POLICY: Topical Products – Vtama and Zoryve Step Therapy Policy
- Vtama® (tapinarof 1% cream – Dermavant)
- Zoryve™ (roflumilast 0.3% cream – Arcutis Biotherapeutics)

REVIEW DATE: 10/11/2023

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.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Vtama, an aryl hydrocarbon receptor agonist, is indicated for the topical treatment of **plaque psoriasis** in adults.[1] Zoryve, a phosphodiesterase 4 (PDE4) inhibitor, is indicated for the topical treatment of **plaque psoriasis**, including intertriginous areas, in patients ≥ 6 years of age.[2]

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] Neither Vtama nor Zoryve is 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.

POLICY STATEMENT

This program has been developed to encourage the use of one or two Step 1 Product(s) prior to the use of a Step 2 Product. A trial of one Step 1a Product (Topical Corticosteroid) and one Step 1b Product (Topical Vitamin D Analog) is required prior to the use of a Step 2 Product; OR a trial of one Step 1c Product (Topical Corticosteroid/Topical Vitamin D Analog combination product) is required prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Topical Products – Vtama and Zoryve product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

Step 1a: Topical Corticosteroids (medium-, medium-high, high-, and/or super-high potency prescription topical corticosteroid) [Brand and Generic Products] {See Table 1}

Table 1. Topical Corticosteroids (Groups 1, 2, 3, and 4).[5]

Generic Name	Strength	Formulations
Group 1: Super-High Potency		
Betamethasone dipropionate, augmented	0.05%	ointment, gel
Clobetasol propionate	0.05%	cream, foam, gel, lotion, ointment, shampoo
Diflorasone diacetate	0.05%	ointment
Fluocinonide	0.1%	cream
Flurandrenolide	4 mcg/m^2	tape
Halobetasol propionate	0.05%	cream, ointment, lotion
Group 2: High Potency		
Amcinonide	0.1%	ointment
Betamethasone dipropionate, augmented	0.05%	cream, lotion
Betamethasone dipropionate	0.05%	cream, ointment
Desoximetasone	0.25%	cream, ointment, spray
	0.05%	gel
Fluocinonide	0.05%	cream, gel, ointment, solution
Halcinonide	0.1%	cream
Mometasone furoate	0.1%	ointment
Triamcinolone acetonide	0.5%	ointment
Group 3: Medium-High Potency		
Amcinonide	0.1%	cream, lotion
Betamethasone valerate	0.1%	ointment
Diflorasone diacetate	0.05%	cream
Fluocinonide-E	0.05%	cream
Fluticasone propionate	0.005%	ointment
Halcinonide	0.1%	ointment
Triamcinolone acetonide	0.5%	cream
Triamcinolone acetonide	0.1%	ointment
Group 4: Medium Potency		
Betamethasone valerate	0.12%	foam

Generic Name	Strength	Formulations
Desoximetasone	0.05%	cream
Fluocinolone acetonide	0.025%	ointment
Flurandrenolide	0.05%	ointment
Hydrocortisone valerate	0.2%	ointment
Mometasone furoate	0.1%	cream, lotion, solution
Prednicarbate	0.1%	ointment

Step 1b: Topical Vitamin D Analogs: calcipotriene 0.005% cream (Dovonex, generic), calcipotriene 0.005% foam, calcipotriene 0.005% ointment, calcipotriene 0.005% solution, calcitriol 3 mcg/g ointment (Vectical, generic), Sorilux

Step 1c: calcipotriene 0.005% and betamethasone dipropionate 0.064% ointment (Taclonex, generic), calcipotriene 0.005% and betamethasone dipropionate 0.064% suspension (Taclonex, generic), Enstilar, Wynzora

Step 2: Vtama, Zoryve

CRITERIA

1. **Vtama.** Approve if the patient meets the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets one of the following (i, ii, or iii):
     - **i.** Patient has tried one Step 1a Product and one Step 1b product; OR
     - **ii.** Patient has tried one Step 1c Product.
     - **iii.** Patient is treating plaque psoriasis affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia and has tried one Step 1b Product.

2. **Zoryve.** Approve if the patient meets the following (A and B):
   - **A)** Patient is ≥ 6 years of age; AND
   - **B)** Patient meets one of the following (i, ii, or iii):
     - **i.** Patient has tried one Step 1a Product and one Step 1b product; OR
     - **ii.** Patient has tried one Step 1c Product; OR
     - **iii.** Patient is treating plaque psoriasis affecting one of the following areas: face, eyes/eyelids, skin folds, and/or genitalia and has tried one Step 1b Product.

REFERENCES

1. Vtama® topical cream [prescribing information]. Long Beach, CA: Dermavant; May 2022.
2. Zoryve™ cream [prescribing information.] Westlake, CA; Arcutis Biotherapeutics: October 2023.
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.
5. Facts and Comparisons® Online. Wolters Kluwer Health; 2021. Available at: https://fco.factsandcomparisons.com/lco/action/home. Accessed on October 09, 2023. Search terms: topical corticosteroids.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	New Policy – effective 01/01/2023	11/16/2022
Early Annual Revision	**Zoryve:** Expanded age criterion for Zoryve from ≥ 12 years to ≥ 6 years of age.	10/11/2023