



STEP THERAPY POLICY

- POLICY:** Topical Vitamin D Analogs Step Therapy Policy
- Calcipotriene 0.005% foam– Trifluent Pharma (authorized generic)
 - Calcipotriene 0.005% solution (generic only)
 - Dovonex[®] (calcipotriene cream 0.005% – LEO Pharma, generic)
 - Enstilar[®] (calcipotriene 0.005% and betamethasone dipropionate 0.064% foam – LEO Pharma)
 - Sorilux[®] (calcipotriene foam 0.005% – Mayne Pharma, generic)
 - Taclonex[®] (calcipotriene 0.005% and betamethasone dipropionate 0.064% ointment – LEO Pharma, generic)
 - Wyzora[®] (calcipotriene 0.005% and betamethasone dipropionate 0.064% cream – MC2 Therapeutics)

REVIEW DATE: 11/15/2023

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

The topical vitamin D analog products are indicated for the treatment of **plaque psoriasis**. The specific indications are as follows:¹⁻¹⁰

- Calcipotriene cream and ointment are indicated for the treatment of **plaque psoriasis of the body in adults**.
- Calcipotriene solution is indicated for the treatment of **plaque psoriasis of the scalp in adults**.
- Dovonex cream is indicated for the treatment of **plaque psoriasis in adults**.
- Enstilar is indicated for the topical treatment of **plaque psoriasis in patients ≥ 12 years** of age.

- Calcipotriene foam 0.005% (authorized generic) and Sorilux is indicated for the topical treatment of **plaque psoriasis of the scalp and body in adults and pediatric patients ≥ 4 years** of age.
- Taclonex ointment is indicated for the topical treatment of **plaque psoriasis in patients ≥ 12 years** of age.
- Wyzora cream is indicated for the topical treatment of **plaque psoriasis in patients ≥ 18 years** of age.

Several of the topical vitamin D analogs are indicated for use in patients < 18 years of age: calcipotriene foam (authorized generic), generic calcipotriene-betamethasone dipropionate ointment, Enstilar foam, Sorilux foam, and Taclonex ointment.

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product 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 Vitamin D Analogs 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 1: generic calcipotriene cream, generic calcipotriene ointment, generic calcipotriene solution

Step 2: generic calcipotriene-betamethasone dipropionate ointment, calcipotriene foam (authorized generic), Dovonex cream, Enstilar foam, Sorilux foam, Taclonex ointment, Wyzora cream

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. If the patient is < 18 years of age, approve calcipotriene foam (authorized generic), generic calcipotriene-betamethasone dipropionate ointment, Enstilar foam, Sorilux foam, or Taclonex ointment.

REFERENCES

1. Calcipotriene cream [prescribing information]. Mahwah, NJ: Glenmark; April 2023.
2. Calcipotriene and betamethasone propionate ointment [prescribing information]. Allegan, MI: Perrigo; January 2020.

3. Dovonex® cream [prescribing information]. Madison, NJ: LEO Pharma.; June 2021.
4. Calcipotriene foam [prescribing information]. Greenville, NC: Mayne Pharma; December 2020.
5. Sorilux® foam [prescribing information]. Greenville, NC: Mayne Pharma; November 2019.
6. Taclonex® ointment [prescribing information]. Madison, NJ: LEO Pharma; January 2023.
7. Taclonex® suspension [prescribing information]. Madison, NJ: LEO Pharma; August 2020.
8. Wyzora® cream [prescribing information]. Dover, DE: MC2 Therapeutics; December 2021.
9. Enstilar® foam [prescribing information]. Madison, NJ: LEO Pharma; April 2022.
10. Calcipotriene solution [prescribing information]. Gurnee, IL: Akorn; June 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/09/2022
Annual Revision	No criteria changes.	11/15/2023

"Cigna Companies" refers to operating subsidiaries of Cigna Corporation. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of Cigna Health Corporation. © 2023 Cigna