MEDICAL MUTUAL®

Drug Policy

Policy: SD **Impacted Drugs:**	**Topical Vitamin D Analogs Preferred Step Therapy** **Calcipotriene foam 0.005% (authorized generic)** **Dovonex (calcipotriene cream 0.005%)** **Enstilar (calcipotriene 0.005% and betamethasone dipropionate 0.064% foam)** **Sorilux (calcipotriene foam 0.005%)** **Taclonex (calcipotriene 0.005% and betamethasone dipropionate 0.064% ointment)** **Wynzora (calcipotriene and betamethasone diproprionate 0.064% cream)**	**Annual Review Date:** **01/18/2024** **Last Revised Date:** **01/18/2024**

OVERVIEW

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

- 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.
- Wynzora 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

A preferred step therapy program has been developed to encourage the use of a preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a history of one preferred Product within the 130-day look-back period is excluded from Step Therapy.

Preferred Medications

- Generic calcipotriene cream
- Generic calcipotriene ointment
- Generic calcipotriene solution

Non-Preferred Medications

- Generic calcipotriene-betamethasone dipropionate ointment
- Calcipotriene foam (authorized generic)
- Dovonex
- Enstilar
- Sorilux
- Taclonex ointment
- Wynzora

PREFERRED STEP THERAPY CRITERIA

1. If the patient has tried a preferred medication, then authorization for a non-preferred medication may be given.
2. If the patient is < 18 years of age, approve generic calcipotriene-betamethasone dipropionate ointment, Taclonex ointment, calcipotriene foam (authorized generic), Enstilar, or Sorilux.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

Step Therapy Exception Criteria
Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:

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1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Calcipotriene cream [prescribing information]. Mahwah, NJ: Glenmark Pharmaceuticals Inc; March 2021.
2. Calcipotriene and betamethasone propionate ointment [prescribing information]. Allegan MI: Perrigo; January, 2020.
3. Dovonex® cream [prescribing information]. Madison, NJ: LEO Pharma Inc.; June 2021.
4. Calcipotriene foam [prescribing information]. San Antonio, TX: Trifluent Pharma LLC; August 2020.
5. Sorilux® foam [prescribing information]. Greenville, NC: Mayne Pharma; November 2019.
6. Taclonex® ointment [prescribing information]. Madison, NJ: LEO Pharma Inc; March 2020.
7. Taclonex® suspension [prescribing information]. Madison, NJ: LEO Pharma Inc; June 2020.
8. Wynzora® cream [prescribing information]. Dover, DE: MC2 Therapeutics, Inc; November 2020.
9. Enstilar® foam [prescribing information]. Madison, NJ: LEO Pharma; August 2021.
10. Calcipotreine solution [prescribing information]. Gurnee, IL: Akorn; June 2022.

11. Calcipotriene. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 13 December 2023. Accessed 16 January 2024.
12. Calcipotriene/betamethasone dipropionate. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 13 December 2023. Accessed 16 January 2024.