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Topical Vitamin D Analogs

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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.

Overview

This policy supports medical necessity review for formulary exceptions to the following topical vitamin D analog non-covered products:

- **calcipotriene** 0.005% foam (Sorilux authorized generic)
- **Calsodore** (calcipotriene 0.005% cream)
- **Dovonex**[®] (calcipotriene 0.005% cream)
- **Enstilar**[®] (calcipotriene 0.005%/ betamethasone 0.064% foam)
- **Sorilux**[™] (calcipotriene 0.005% foam)
- **Taclonex**[®] (calcipotriene 0.005%/ betamethasone 0.064% ointment)
- **Vectical**[™] (calcitriol 3 mcg/Gm ointment)
- **Wynzora**[®] (calcipotriene/ betamethasone dipropionate 0.005%/0.064% topical cream)

Coverage for topical vitamin D products varies across plans and requires the use of preferred products in addition to the criteria listed below. Refer to the customer's benefit plan document for coverage details.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage criteria are listed for products in below table:

Employer Group Non-Preferred Products and Criteria:

Non-Preferred Product	Criteria
calcipotriene 0.005% foam	<p>Calcipotriene foam is considered medically necessary for the treatment of plaque psoriasis when the individual meets ONE of the following criteria:</p> <ol style="list-style-type: none"> 1. Between the ages of 4 and 18 years 2. Failure or intolerance to calcipotriene cream, ointment, or solution
<p>Calsodore (calcipotriene 0.005% cream)</p>	<p>Calsodore is considered medically necessary for the treatment of plaque psoriasis when the individual has had a trial of calcipotriene 0.005% cream (generic for Dovonex) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction.</p>
<p>Dovonex (calcipotriene 0.005% cream)</p>	<p><u>Value/Advantage/Cigna Total Savings</u></p> <p>Dovonex cream is considered medically necessary for the treatment of plaque psoriasis when the individual has had a trial of calcipotriene cream (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction</p>
<p>Enstilar (calcipotriene 0.005%/betamethasone 0.064% foam)</p>	<p>Enstilar foam is considered medically necessary for the treatment of plaque psoriasis when the individual meets ONE of the following criteria:</p> <ol style="list-style-type: none"> 1. Between the ages of 12 and 18 years 2. Failure or intolerance to BOTH of the following: <ol style="list-style-type: none"> a. calcipotriene/betamethasone topical suspension or ointment b. A calcipotriene-containing product in combination with FOUR different generic prescription strength topical corticosteroid products
<p>Sorilux (calcipotriene 0.005% foam)</p>	<p>Sorilux foam is considered medically necessary for the treatment of plaque psoriasis when the individual meets ONE of the following criteria:</p> <ol style="list-style-type: none"> 1. Between the ages of 4 and 18 years 2. Failure or intolerance to calcipotriene cream, ointment, or solution
<p>Taclonex (calcipotriene 0.005%/betamethasone 0.064% ointment)</p>	<p>Taclonex ointment is considered medically necessary for the treatment of plaque psoriasis when the individual meets ONE of the following criteria:</p> <ol style="list-style-type: none"> 1. Between the ages of 12 and 18 years 2. Failure or intolerance to BOTH of the following: <ol style="list-style-type: none"> a. A trial of calcipotriene/betamethasone ointment (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction

Non-Preferred Product	Criteria
	<p>b. A calcipotriene-containing product in combination with FOUR different generic prescription strength topical corticosteroid products</p>
<p>Vectical (calcitriol 3 mcg/gm ointment)</p>	<p><u>Value/Advantage/Cigna Total Savings</u></p> <p>Vectical ointment is considered medically necessary for the treatment of plaque psoriasis when the individual has had a trial of calcitriol ointment (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction</p>
<p>Wynzora (calcipotriene/ betamethasone dipropionate 0.005%/0.064% topical cream)</p>	<p>Wynzora is considered medically necessary for the treatment of plaque psoriasis when the individual meets the following criteria:</p> <ol style="list-style-type: none"> 1. Failure or intolerance to calcipotriene-containing product in combination with FIVE different generic prescription strength topical corticosteroid products

Individual and Family Plan Non-Preferred Products and Criteria:

Non-Preferred Product	Criteria
<p>Calsodore (calcipotriene 0.005% cream)</p>	<p>Calsodore is considered medically necessary for the treatment of plaque psoriasis when the individual has had a trial of calcipotriene 0.005% cream (generic for Dovonex) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction.</p>

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of Topical vitamin D analogs is considered medically necessary for plaque psoriasis when initial criteria are met AND beneficial response is demonstrated.

Authorization Duration

Initial approval duration: up to 12 months
 Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven.

Background

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.

References

1. Calcipotriene cream [prescribing information]. Mahwah, NJ: Glenmark; March 2021.
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]. San Antonio, TX: Trifluent Pharma; August 2020.
5. Sorilux[®] foam [prescribing information]. Greenville, NC: Mayne Pharma; November 2019.
6. Taclonex[®] ointment [prescribing information]. Madison, NJ: LEO Pharma; March 2020.
7. Wyzora[®] cream [prescribing information]. Dover, DE: MC2 Therapeutics; November 2020.
8. Enstilar[®] foam [prescribing information]. Madison, NJ: LEO Pharma; August 2021.
9. Calcipotriene solution [prescribing information]. Gurnee, IL: Akorn; June 2022.

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