

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	VITAMIN D ANALOGS TOPICAL
BRAND NAME* (generic)	(calcipotriene topical scalp solution)
	CALCITRENE (calcipotriene ointment)
	DOVONEX (calcipotriene cream)
	ENSTILAR (calcipotriene/betamethasone dipropionate foam)
	SORILUX (calcipotriene foam)
	TACLONEX (calcipotriene/betamethasone dipropionate ointment, suspension)
	VECTICAL (calcitriol ointment)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

Ref # 1339-A

* Drugs that are listed in the target drug box include both brand and generic and all dosages forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.

FDA-APPROVED INDICATIONS

Calcipotriene Topical Scalp Solution

Calcipotriene Topical Solution, 0.005% (Scalp Solution) is indicated for the topical treatment of chronic, moderately severe psoriasis of the scalp. The safety and effectiveness of topical calcipotriene in dermatoses other than psoriasis have not been established.

Calcitrene

Calcitrene (calcipotriene) ointment, 0.005% is indicated for the treatment of plaque psoriasis in adults. The safety and effectiveness of topical calcipotriene in dermatoses other than psoriasis have not been established.

Dovonex

Dovonex (calcipotriene) Cream, 0.005%, is indicated for the treatment of plaque psoriasis. The safety and effectiveness of topical calcipotriene in dermatoses other than psoriasis have not been established.

Enstilar

Enstilar (calcipotriene and betamethasone dipropionate) Foam is indicated for the topical treatment of plaque psoriasis in patients 12 years of age and older.

Vitamin D Analog Topical_PA_ALL_Rx

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Sorilux

Sorilux foam is indicated for the topical treatment of plaque psoriasis of the scalp and body in patients 12 years and older.

Taclonex Ointment

Taclonex Ointment is indicated for the topical treatment of plaque psoriasis in patients 12 years of age and older.

Taclonex Topical Suspension

Taclonex Topical Suspension is indicated for the topical treatment of plaque psoriasis of the scalp and body in patients 12 years and older.

Vectical

Vectical Ointment is indicated for the topical treatment of mild to moderate plaque psoriasis in adults 18 years and older.

Limitations of Use

Vectical Ointment should not be applied to the eyes, lips, or facial skin.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the treatment of psoriasis
- AND**
- The patient has experienced an inadequate treatment response, intolerance, or contraindication to a generic topical steroid (e.g., betamethasone dipropionate, clobetasol propionate, desoximetasone, or fluocinonide)

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Topical Vitamin D Analogs are indicated for the treatment of plaque psoriasis. Calcipotriene 0.005% topical scalp solution is indicated for the topical treatment of chronic, moderately severe psoriasis of the scalp.¹⁻¹⁰

According to the American Academy of Dermatology (AAD) Guidelines of Care for the Management of Psoriasis and Psoriatic Arthritis, topical corticosteroids are the cornerstone of treatment for the majority of patients with psoriasis, particularly those with limited disease. Corticosteroids are available in many strengths and formulations, which allows for versatility of use. The choice of the appropriate potency corticosteroid and its vehicle should take into consideration the disease severity, the location being treated, patient preference, as well as the age of the patient.¹² The vitamin D analogs are another first-line topical agent with proven efficacy in the treatment of psoriasis. Vitamin D analogs have a slower onset of action than topical corticosteroids, but tend to yield longer disease-free periods. A systematic review of calcipotriol ointment demonstrated that only potent topical corticosteroids (e.g., betamethasone dipropionate, clobetasol propionate, desoximetasone, or fluocinonide) have comparable or greater efficacy after 8 weeks of treatment.¹¹

REFERENCES

1. Calcipotriene Topical Scalp Solution [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; June 2019.
2. Calcitrene Ointment [package insert]. Hawthorne, NY: Taro Pharmaceuticals U.S.A., Inc.; January 2019.
3. Dovonex Cream [package insert]. Madison, NJ: LEO Pharma Inc.; October 2018.
4. Enstilar Foam [package insert]. Madison, NJ: LEO Pharma Inc.; August 2019.
5. Sorilux [package insert]. Greenville, NC: Mayne Pharma.; May 2019.
6. Taclonex Ointment [package insert]. Madison, NJ: LEO Pharma Inc.; December 2018.
7. Taclonex Topical Suspension [package insert]. Madison, NJ: LEO Pharma Inc.; August 2019.
8. Vectical Ointment [package insert]. Fort Worth, Texas: Galderma Laboratories, L.P.; July 2018.
9. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed June 2019.
10. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed June 2019.

11. Menter A, Korman N, Elmets C, et al. American Academy of Dermatology Work Group. Guidelines of Care for the Management of Psoriasis and Psoriatic Arthritis: Section 6. Guidelines of Care for the Treatment of Psoriasis and Psoriatic Arthritis: Case-Based Presentations and Evidence-Based Conclusions. *J Am Acad Dermatol*. 2011; 65(1):137-74.
12. Menter A, Korman N, Elmets C, et al. Guidelines of Care for the Management of Psoriasis and Psoriatic Arthritis. Section 3. Guidelines of Care for the Management and Treatment of Psoriasis with Topical therapies. *J Am Acad Dermatol* 2009; 60:643-59.

Written by: UM Development (CT)
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 External Review: 03/2016, 10/2017, 10/2018, 08/2019

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for the treatment of psoriasis?	Yes	No
2	Has the patient experienced an inadequate treatment response, intolerance, or contraindication to a generic topical steroid (e.g., betamethasone dipropionate, clobetasol propionate, desoximetasone, or fluocinonide)?	Yes	No

Mapping Instructions			
	Yes	No	DENIAL REASONS – DO NOT USE FOR MEDICARE PART D
1.	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this drug when it is used for psoriasis. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis.]
2.	Approve, 12 months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have tried a generic topical steroid and it either did not work for you or you cannot use it. Your request has been denied based on the information we have. [Short Description: No trial of a generic topical steroid.]