Reference number(s)

1381-E

# Initial Step Therapy with Quantity Limit; Post Step Therapy Prior Authorization with Quantity Limit Vitamin D Analogs Topical

# **Products Referenced by this Document**

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
calcipotriene cream (brand unavailable)	calcipotriene cream	cream
calcipotriene topical solution (brand unavailable)	calcipotriene topical solution	scalp solution
Calcitrene	calcipotriene	ointment
Enstilar	calcipotriene/betamethasone dipropionate	foam
Sorilux	calcipotriene	foam
Taclonex	calcipotriene/betamethasone dipropionate	ointment, suspension
Vectical	calcitriol	ointment
Wynzora	calcipotriene/betamethasone dipropionate	cream

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# **Indications**

# **FDA-approved Indications**

#### Calcipotriene Cream

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.

#### Calcipotriene Topical 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.

#### **Fnstilar**

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

#### Sorilux

Sorilux Foam is indicated for the topical treatment of plaque psoriasis of the scalp and body in adults and pediatric patients 4 years of age 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 and pediatric patients 2 years and older.

#### **Limitations of Use**

The safety and effectiveness of Vectical Ointment in patients with known or suspected disorders of calcium metabolism have not been evaluated.

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#### Wynzora

Wynzora Cream is indicated for the topical treatment of plaque psoriasis in patients 18 years of age and older.

# Initial Step Therapy/Initial Step Therapy with Quantity Limit

Include Rx and OTC products unless otherwise stated.

If the patient has filled a prescription for at least a 30-day supply of a topical steroid within the past 180 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria or exceeds the initial quantity limit, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

If the patient meets the initial step therapy criteria, then the initial limit criteria will apply. If the patient is requesting more than the initial quantity limit the claim will reject with a message indicating that a PA is required.

#### Initial Limit Criteria

Limits do not accumulate together; patient is allowed the maximum limit for each drug and strength

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Brand Sorilux Foam is only available in a 120 gram can. Generic calcipotriene foam is available in a 60 gram can. All requests for brand Sorilux Foam will be considered through post limit prior authorization. Please see Post Limit Quantity Chart.

Drug	1 Month Limit	3 Month Limit
calcipotriene cream 0.005%	60 grams / 25 days	180 grams / 75 days
calcipotriene topical solution 0.005%	60 mL / 25 days	180 mL / 75 days
Calcitrene (calcipotriene) Topical Ointment 0.005%	60 grams / 25 days	180 grams / 75 days
Enstilar (calcipotriene/betamethasone diproprionate) Foam 0.005%/0.064%	60 grams / 25 days	180 grams / 75 days

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Drug	1 Month Limit	3 Month Limit
Sorilux (calcipotriene) Foam 0.005%	60 grams / 25 days	180 grams / 75 days
Taclonex (calcipotriene/betamethasone diproprionate) Ointment 0.005%/0.064%	60 grams / 25 days	180 grams / 75 days
Taclonex (calcipotriene/betamethasone diproprionate) Suspension 0.005%/0.064%	60 grams / 25 days	180 grams / 75 days
Vectical (calcitriol) Ointment 3 mcg/g	100 grams / 25 days	300 grams / 75 days
Wynzora (calcipotriene/betamethasone diproprionate) Cream 0.005%/0.064%	60 grams / 25 days	180 grams / 75 days

# **Coverage Criteria**

#### **Psoriasis**

Authorization may be granted when the requested drug is being prescribed for the treatment of psoriasis when ALL of the following criteria are met:

- The patient has experienced an inadequate treatment response, intolerance, or contraindication to a topical steroid.
- The patient meets ONE of the following:
  - If additional quantities are being requested, then Vectical Ointment is being prescribed to treat a body surface area that requires MORE than 100 grams per month.
  - If additional quantities are being requested, then calcipotriene cream, calcipotriene topical solution, Calcitrene Topical Ointment, Enstilar Foam, Sorilux Foam, Taclonex Ointment, Taclonex Suspension, or Wynzora Cream is being prescribed to treat a body surface area that requires MORE than 60 units per month.

# **Continuation of Therapy**

#### **Psoriasis**

Authorization may be granted when the requested drug is being prescribed for the treatment of psoriasis when ALL of the following criteria are met:

• The patient has achieved or maintained a positive clinical response to the requested drug (e.g., clear, or almost clear outcome, patient satisfaction, etc.).

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- The patient meets ONE of the following:
  - If additional quantities are being requested, then Vectical Ointment is being prescribed to treat a body surface area that requires MORE than 100 grams per month.
  - If additional quantities are being requested, then calcipotriene cream, calcipotriene topical solution, Calcitrene Topical Ointment, Enstilar Foam, Sorilux Foam, Taclonex Ointment, Taclonex Suspension, or Wynzora Cream is being prescribed to treat a body surface area that requires MORE than 60 units per month.

# **Quantity Limits Apply**

# Post Limit Quantity

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Drug	1 Month Limit	3 Month Limit
calcipotriene cream 0.005%	120 grams / 25 days	360 grams / 75 days
calcipotriene topical solution 0.005%	120 mL / 25 days	360 mL / 75 days
Calcitrene (calcipotriene) Topical Ointment 0.005%	120 grams / 25 days	360 grams / 75 days
Enstilar (calcipotriene/betamethasone diproprionate) Foam 0.005%/0.064%	120 grams / 25 days	360 grams / 75 days
Sorilux (calcipotriene) Foam 0.005%	120 grams / 25 days	360 grams / 75 days
Taclonex (calcipotriene/betamethasone diproprionate) Ointment 0.005%/0.064%	120 grams / 25 days	360 grams / 75 days
Taclonex (calcipotriene/betamethasone diproprionate) Suspension 0.005%/0.064%	120 grams / 25 days	360 grams / 75 days
Vectical (calcitriol) Ointment 3 mcg/g	200 grams / 25 days	600 grams / 75 days
Wynzora (calcipotriene/betamethasone diproprionate) Cream 0.005%/0.064%	120 grams / 25 days	360 grams / 75 days

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# **Duration of Approval (DOA)**

1381-E: Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months

### References

- 1. Calcipotriene Cream [package insert]. Memphis, TN: Northstar Rx LLC; April 2023.
- 2. Calcipotriene Topical Solution [package insert]. South Plainfield, NJ: Cosette Pharmaceuticals, Inc.; February 2021.
- Calcitrene Ointment [package insert]. Hawthorne, NY: Taro Pharmaceuticals U.S.A., Inc.; November 2011.
- 4. Enstilar Foam [package insert]. Madison, NJ: LEO Pharma Inc.; April 2022.
- 5. Sorilux [package insert]. Greenville, NC: Mayne Pharma.; April 2024.
- 6. Taclonex Ointment [package insert]. Madison, NJ: LEO Pharma Inc.; January 2023.
- 7. Taclonex Topical Suspension [package insert]. Madison, NJ: LEO Pharma Inc.; August 2020.
- 8. Vectical Ointment [package insert]. Dallas, TX: Galderma Laboratories, L.P.; October 2022.
- 9. Wynzora Cream [package insert]. Charleston, SC; EPI Health, LLC..; November 2023.
- 10. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com. Accessed June 3, 2025.
- 11. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 06/03/2025).
- 12. Elmets C, Korman, N, 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. 2020;84:432-470.
- 13. Eichenfield L, Tom W, Berger T, et al. Guidelines of care for the management of atopic dermatitis: Section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol 2014;71:116-32.
- 14. U.S. Department of Health & Human Services. Burn Triage and Treatment Thermal Injuries. Chemical Hazards Emergency Medical Management. February 21, 2025. Available at: https://chemm.hhs.gov/burns.htm. Accessed May 14, 2025.