

# Initial Step Therapy; Post Step Therapy Prior Authorization Tacrolimus Ointment with Age

## 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
tacrolimus (brand unavailable)	tacrolimus	ointment

## Indications

### FDA-approved Indications

Tacrolimus ointment, both 0.03% and 0.1% for adults, and only 0.03% for children aged 2 to 15 years, is indicated as second-line therapy for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis in non-immunocompromised adults and children who have failed to respond adequately to other topical prescription treatments for atopic dermatitis, or when those treatments are not advisable.

Tacrolimus ointment is not indicated for children younger than 2 years of age.

### Compendial Uses

Psoriasis<sup>3</sup> - on the face, genitals, or skin folds.<sup>5</sup>

Vitiligo on the head or neck.<sup>3,6,7</sup>

Atopic Dermatitis for patients under 2 years of age (tacrolimus ointment 0.03%).<sup>3,4</sup>

# Initial Step Therapy

Include Prescription (Rx) and Over-the-counter (OTC) products unless otherwise stated.

For tacrolimus 0.1% ointment, the patient must be at least 16 years of age. For tacrolimus 0.03% ointment, there is no age restriction. Additionally, if the patient has filled a prescription for at least a 14-day supply of at least one corticosteroid of medium or higher potency within the past 180 days (see examples in Table 1) 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, then the system 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.

**Table 1: Examples of Topical Corticosteroids for Treatment of Atopic Dermatitis** <sup>2,3,4</sup>

Medium Potency	betamethasone dipropionate lotion, spray 0.05%
Medium Potency	betamethasone valerate cream/lotion 0.1%/foam 0.12%
Medium Potency	clocortolone pivalate cream 0.1%
Medium Potency	desonide lotion, ointment 0.05%
Medium Potency	desoximetasone cream 0.05%
Medium Potency	fluocinolone acetonide cream/ointment/kit 0.025%
Medium Potency	flurandrenolide cream/ointment/lotion 0.05%
Medium Potency	fluticasone propionate cream/lotion 0.05%/ointment 0.005%
Medium Potency	hydrocortisone butyrate cream/lipocream/lotion/ointment/solution 0.1%
Medium Potency	hydrocortisone probutate cream 0.1%
Medium Potency	hydrocortisone valerate cream/ointment 0.2%
Medium Potency	mometasone furoate cream/lotion/solution 0.1%
Medium Potency	prednicarbate cream/ointment 0.1%
Medium Potency	triamcinolone acetonide cream/ointment/lotion/kit 0.1%
Medium Potency	triamcinolone acetonide cream/ointment/lotion 0.025%
Medium Potency	triamcinolone acetonide ointment 0.05%
High Potency	amcinonide cream/ointment/lotion 0.1%
High Potency	betamethasone dipropionate cream/ointment 0.05%
High Potency	betamethasone dipropionate augmented cream/lotion 0.05%
High Potency	betamethasone valerate ointment 0.1%
High Potency	desoximetasone cream/ointment/spray 0.25%/gel/ointment 0.05%

High Potency	diflorasone diacetate cream (emollient base) 0.05% diflorasone cream 0.05%
High Potency	halcinonide cream/ointment 0.1%
High Potency	fluocinonide cream/emulsified cream/ointment/gel/solution 0.05%
High Potency	mometasone furoate ointment 0.1%
High Potency	triamcinolone acetonide cream/ointment 0.5%
High Potency	triamcinolone acetonide aerosol solution 0.147 mg/g
Very High Potency	betamethasone dipropionate augmented ointment/gel 0.05%
Very High Potency	clobetasol propionate cream/ointment/foam/shampoo/gel/lotion/solution/spray 0.05%/cream 0.025%
Very High Potency	diflorasone diacetate ointment 0.05%
Very High Potency	flurandrenolide tape 4 mcg/cm <sup>2</sup>
Very High Potency	halobetasol propionate cream/ointment/lotion/kit 0.05%
Very High Potency	fluocinonide cream 0.1%

## Coverage Criteria

### Atopic Dermatitis (Eczema)

Authorization may be granted when the requested drug is being prescribed for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis (eczema) when ONE of the following criteria is met:

- The request is for tacrolimus 0.03% ointment and ONE of the following criteria is met:
  - The patient is less than 2 years of age.
  - The requested drug will be used on sensitive skin areas (e.g., face, genitals, or skin folds).
  - The patient has experienced an inadequate treatment response, intolerance, or contraindication to at least ONE first line therapy agent (e.g., medium or higher potency topical corticosteroid).
- The request is for tacrolimus 0.1% ointment and the following criteria are met:
  - The patient is 16 years of age or older and ONE of the following criteria is met:
    - The requested drug will be used on sensitive skin areas (e.g., face, genitals, or skin folds).
    - The patient has experienced an inadequate treatment response, intolerance, or contraindication to at least ONE first line therapy agent (e.g., medium or higher potency topical corticosteroid).

## Psoriasis

Authorization may be granted when the requested drug is being prescribed for psoriasis on the face, genitals, or skin folds when ONE of the following criteria is met:

- The request is for tacrolimus 0.03% ointment.
- The request is for tacrolimus 0.1% ointment and the following criteria is met:
  - The patient is 16 years of age or older.

## Vitiligo

Authorization may be granted when the requested drug is being prescribed for vitiligo on the head or neck when ONE of the following criteria is met:

- The request is for tacrolimus 0.03% ointment.
- The request is for tacrolimus 0.1% ointment and the following criteria is met:
  - The patient is 16 years of age or older.

# Continuation of Therapy

## Atopic Dermatitis

Authorization may be granted when the requested drug is being prescribed for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis (eczema) when the following criteria is met:

- The patient has achieved or maintained a positive clinical response as evidenced by improvement [e.g., improvement in or resolution of any of the following signs and symptoms: erythema (redness), edema (swelling), xerosis (dry skin), erosions, excoriations (evidence of scratching), oozing and crusting, lichenification (epidermal thickening), OR pruritus (itching)] and ONE of the following criteria is met:
  - The request is for tacrolimus 0.03% ointment.
  - The request is for tacrolimus 0.1% ointment and the following criteria is met:
    - The patient is 16 years of age or older.

## Psoriasis

Authorization may be granted when the requested drug is being prescribed for psoriasis on the face, genitals, or skin folds when the following criteria is met:

- The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., clear, or almost clear outcome, patient satisfaction, etc.) and ONE of the following criteria is met:

- The request is for tacrolimus 0.03% ointment.
- The request is for tacrolimus 0.1% ointment and the following criteria is met:
  - The patient is 16 years of age or older.

## Vitiligo

Authorization may be granted when the requested drug is being prescribed for vitiligo on the head or neck when the following criteria is met:

- The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., meaningful repigmentation) and ONE of the following criteria is met:
  - The request is for tacrolimus 0.03% ointment.
  - The request is for tacrolimus 0.1% ointment and the following criteria is met:
    - The patient is 16 years of age or older.

## Duration of Approval (DOA)

- 177-F:
  - 2 years of age and older: Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months
  - Less than 2 years of age: DOA: 3 months
- 1254-F:
  - 2 years of age and older: Initial therapy DOA: 3 months; Continuation of therapy DOA: 36 months
  - Less than 2 years of age: DOA: 3 months

## References

1. Tacrolimus Ointment [package insert]. Melville, NY: Fougera PHARMACEUTICALS INC; September 2021.
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3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 02/05/2025).
4. Eichenfield L, Tom W, 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.
5. Elmetts CA, Korman NJ, Prater EF, 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. 2021 Feb;84(2):432-470.

Reference number(s)
1254-F, 177-F

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7. Eleftheriadou V, Atkar R, et al. British Association of Dermatologists guidelines for the management of people with vitiligo 2021. *The British Journal of Dermatology*. 2021;186(1):18-29.
8. Eichenfield LF, Tom WL, et. al. Guidelines of Care for the Management of Atopic Dermatitis: Section 1. Diagnosis and Assessment of Atopic Dermatitis. *J Am Acad Dermatol* 2014; 70:338-51.
9. Sidbury RS, Alikhan A, Berovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. *J Am Acad Dermatol*. 2023; 89(1): e1-e20.