

PRIOR AUTHORIZATION CRITERIA

BRAND NAME

(generic)

(tacrolimus ointment)

Status: CVS Caremark® Criteria

Type: Initial Prior Authorization

POLICY

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

Psoriasis³ - on the face, genitals, or skin folds⁵

Vitiligo on the head or neck^{3,6,7}

Atopic Dermatitis for patients under 2 years of age (tacrolimus ointment 0.03%)^{3,4}

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 are 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 is 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 are 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 are 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

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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)

- 492-A:
 - 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
- 1255-A:
 - 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

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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.
6. Kubelis-López DE, Zapata-Salazar NA, et al. Updates and new medical treatments for vitiligo (Review). *Exp Ther Med*. 2021;22(2):797.
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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.