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ARBCBS TACROLIMUS PA

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[3] - on the face, genitals, or skin folds[5]
Atopic Dermatitis for patients under 2 years of age (tacrolimus ointment 0.03%)[3,4]

INITIAL STEP THERAPY

**Include Rx and OTC products unless otherwise stated.*

For Protopic (tacrolimus) 0.1%, the patient must be at least 16 years of age. For Protopic (tacrolimus) 0.03%, 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 2,3,4

Potency	Drug
Medium Potency	betamethasone dipropionate lotion, spray 0.05%
	betamethasone valerate crm/lotion 0.1%/foam 0.12%
	clocortolone pivalate crm 0.1%
	desonide lotion, ointment 0.05%
	desoximetasone crm 0.05%
	fluocinolone acetonide crm/oint/kit 0.025%
	flurandrenolide crm/oint/lotion 0.05%
	fluticasone propionate crm/lotion 0.05%/oint 0.005%
	hydrocortisone butyrate cream/lipocream/lotion/oint/soln 0.1%
	hydrocortisone probutate crm 0.1%
	hydrocortisone valerate crm/oint 0.2%
	mometasone furoate crm/lotion/solution 0.1%
	prednicarbate crm/oint 0.1%
	triamcinolone acetonide crm/oint/lotion/kit 0.1%
	triamcinolone acetonide crm/oint/lotion 0.025%
	triamcinolone acetonide ointment 0.05%
High Potency	amcinonide crm/oint/lotion 0.1%
	betamethasone dipropionate crm/oint 0.05%
	betamethasone dipropionate augmented crm/lotion 0.05%
	betamethasone valerate oint 0.1%
	desoximetasone crm/oint/spray 0.25%/gel/oint 0.05%
	diflorasone diacetate crm (emollient base) 0.05% diflorasone cream 0.05%
	halcinonide crm/oint 0.1%
	fluocinonide crm/emulsified cream/oint/gel/soln 0.05%
	mometasone furoate oint 0.1%
	triamcinolone acetonide crm/oint 0.5%
	triamcinolone acetonide aerosol soln 0.147 mg/g
Very High Potency	betamethasone dipropionate augmented oint/gel 0.05%
	clobetasol propionate crm/oint/foam/shampoo/gel/lotion/soln/spray 0.05%/cream 0.025%
	diflorasone diacetate oint 0.05%
	flurandrenolide tape 4mcg/cm^2
	halobetasol propionate crm/oint/lotion/kit 0.05%
	fluocinonide crm 0.1%

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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

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

DURATION OF APPROVAL (DOA)

- 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

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