

# STEP THERAPY CRITERIA

<b>BRAND NAME</b> (generic)	<b>PROTOPIC</b> (tacrolimus)	
<b>Status: CVS Caremark Criteria</b> <b>1254-F</b>		<b>Ref #</b>
<b>Type: Initial Step Therapy; Post Step Therapy Prior Authorization</b> <b>MMT 177-F</b>		<b>Ref #</b>

**POLICY**

**FDA-APPROVED INDICATIONS**

Protopic 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.

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

**Compendial Uses:**

Psoriasis on the face, genitals, or skin folds.<sup>2,3,6,7</sup>  
Vitiligo on the head or neck.<sup>2,3,8,9</sup>

**INITIAL STEP THERAPY**

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 a 14 day supply of at least one corticosteroid of medium or higher potency within the past 180 days (see 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.

Medium Potency		High Potency	
	betamethasone valerate crm/lotion 0.1%/foam 0.12%		amcinonide crm/oint/lotion 0.1%
	betamethasone dipropionate lotion 0.05%		betamethasone dipropionate crm/oint 0.05%
	clocortolone pivalate crm 0.1%		betamethasone dipropionate augmented crm/lotion 0.05%
	desonide lotion, ointment 0.05%		betamethasone valerate oint 0.1%
	desoximetasone crm 0.05%		desoximetasone crm/oint/spray 0.25%/gel/oint 0.05%
	fluocinolone acetonide crm/oint/kit 0.025%		diflorasone diacetate crm (emollient base) 0.05%
	flurandrenolide crm/oint/lotion 0.05%		halcinonide crm/oint 0.1%

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	flurandrenolide tape 4mcg/cm <sup>2</sup>		fluocinonide crm/oint/gel/soln 0.05%
	fluticasone propionate crm/lotion 0.05%/oint 0.005%		triamcinolone acetonide crm/oint 0.5%
	hydrocortisone butyrate oint/soln/lotion/cream 0.1%	Very High Potency	betamethasone dipropionate augmented oint/gel 0.05%
	hydrocortisone probutate crm 0.1%		clobetasol propionate crm/oint/foam/shampoo/gel/lotion/soln/spray 0.05%
	hydrocortisone valerate crm/oint 0.2%		diflorasone diacetate oint 0.05%
	mometasone furoate crm/oint/lotion 0.1%		halobetasol propionate crm/oint 0.05%
	prednicarbate crm/oint 0.1%		fluocinonide crm 0.1%
	triamcinolone acetonide aerosol soln 0.147 mg/g		
	triamcinolone acetonide crm/oint/lotion/kit 0.1%		
	triamcinolone acetonide crm/oint/lotion 0.025%		
	triamcinolone acetonide ointment 0.05%		

### **COVERAGE CRITERIA (MMT 177-F and 1254-F)**

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

- The requested drug is being prescribed for psoriasis on the face, genitals, or skin folds or vitiligo on the head or neck

**OR**

- The requested drug is being prescribed for moderate to severe atopic dermatitis (eczema)

**AND**

- The requested drug will be used on the face, body skin folds, genital area, armpit, or around the eyes

**OR**

- 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 steroid)

**OR**

- The patient is less than 2 years of age

**AND**

- If the request is for Protopic (tacrolimus) 0.1% ointment, the patient is 16 years of age or older

### **REFERENCES**

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