

Topical Agents for Inflammatory Skin Disease

Goal(s):

- Restrict dermatological drugs only for funded OHP diagnoses for adults. Treatments are funded on the OHP for severe inflammatory skin diseases including: psoriasis, atopic dermatitis, lichen planus, Darier disease, pityriasis rubra pilaris, discoid lupus and vitiligo. Treatments for mild or moderate psoriasis, mild or moderate atopic dermatitis, seborrheic dermatitis, keratoderma and other hypertrophic and atrophic conditions of skin are not funded.
- Allow case-by-case review for members covered under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) program.

Length of Authorization:

- From 6 to 12 months

Requires PA:

- Non-preferred topical medications for inflammatory skin conditions.
- All topical medications approved for treatment of atopic dermatitis, psoriasis, and vitiligo for adults 21 years and older.
- This PA does not apply to oral or injectable targeted immune modulators for psoriasis or atopic dermatitis which are subject to separate clinical PA criteria.

Covered Alternatives:

- Preferred alternatives listed at www.orpd.org/drugs/

Table 1. FDA-Approved Ages and Evidence-supported Indications for Topical Drugs

Generic Drug Name	Brand Name	Minimum Age	Indication (severity)
Crisaborole 2% ointment	EUCRISA	3 months	Atopic Dermatitis (Mild-to-Moderate)
Pimecrolimus 1% cream	ELIDEL	2 years	Atopic Dermatitis (Mild-to-Moderate)
Ruxolitinib 1.5% cream	OPZELURA	12 years	Atopic Dermatitis (Mild-to-Moderate) Nonsegmental Vitiligo
Tacrolimus 0.03% ointment	PROTOPIC	2 years	Atopic Dermatitis (Moderate-to-Severe)
Tacrolimus 0.1% ointment	PROTOPIC	16 years	Atopic Dermatitis (Moderate-to-Severe)
Roflumilast 0.3% cream Roflumilast 0.3% cream Roflumilast 0.3% foam	ZORYVE	6 years 6 years 9 years	Atopic Dermatitis Plaque Psoriasis Seborrheic Dermatitis
Tapinarof 1% cream	VTAMA	18 years	Plaque Psoriasis
Calcipotriene cream, solution, and ointment Calcipotriene foam	DOVONEX SORILUX	18 years 4 years	Plaque Psoriasis
Tazarotene cream and gel	TAZORAC	12 years	Plaque Psoriasis
Calcipotriene/Betamethasone ointment, suspension, foam Calcipotriene/Betamethasone cream	TACLONEX ENSTILAR WYNZORA	12 years 18 years	Plaque Psoriasis
Anthralin Shampoo Anthralin Cream	ZITHRANOL	12 years 18 years	Plaque Psoriasis
Halobetasol propionate/Tazarotene Lotion	DUOBRII	18 years	Plaque Psoriasis
Calcitriol ointment	VECTICAL	2 years	Plaque Psoriasis

Table 2. Topical First-Line Treatment Options Based on Disease Severity

Atopic Dermatitis (AD)	Mild to Moderate AD: Low-, Medium-, or High-Potency Corticosteroids* for 2-4 weeks or Calcineurin Inhibitors (pimecrolimus, tacrolimus) Severe AD: High to Super-High Potency Corticosteroids for 2 weeks or Tacrolimus
Plaque Psoriasis (PsO)	Mild to Moderate PsO: Moderate- to High-Potency Corticosteroids* for 4 weeks, Calcineurin Inhibitors (pimecrolimus, tacrolimus) for 8 weeks, Vitamin D Analogues (calcitriol, calcipotriene) for 4 weeks, or Tazarotene for 8 weeks ¹

	Severe PsO: High to Super-High Potency Corticosteroids for 4 weeks ¹
Nonsegmental Vitiligo	Mild to Severe Vitiligo: Moderate- to High-Potency Corticosteroids* for 2 months or Calcineurin Inhibitors (pimecrolimus, tacrolimus) for 3 months ²
Note: *Strength of corticosteroid determined by patient age, site of inflammation, and severity of the condition	

Table 3. Potency of topical corticosteroid preparations using U.S. classification³

Potency Group	Corticosteroid	Strength	Formulation
Lowest Potency (Group 7)	Hydrocortisone Base and Hydrocortisone Acetate	0.5%, 1.0%, 2.0%	cream, ointment, gel, lotion, solution
Low Potency (Group 6)	Alcometasone dipropionate	0.05%	cream, ointment
	Betamethasone valerate	0.05%	lotion
	Desonide	0.05%	cream
	Fluocinolone acetonide	0.01%	cream, oil, shampoo, solution
	Triamcinolone acetonide	0.1%	cream
Medium-Low Potency (Group 5)	Betamethasone dipropionate	0.05%	lotion
	Betamethasone valerate	0.1%	cream
	Betamethasone valerate	0.01%	cream, lotion
	Desonide	0.05%	lotion, ointment
	Fluocinolone acetonide	0.025%	cream
	Flurandrenolide	0.05%	cream
	Fluticasone propionate	0.05%	cream
	Hydrocortisone butyrate	0.1%	cream
	Hydrocortisone valerate	0.2%	cream
	Prednicarbate	0.1%	cream
	Triamcinolone acetonide	0.1%	lotion
Medium Potency (Group 4)	Betamethasone valerate	0.12%	foam
	Desoximetasone	0.05%	cream
	Fluocinolone acetonide	0.025%	ointment
	Fluocinolone acetonide	0.2%	cream
	Flurandrenolide	0.05%	ointment
	Halcinonide	0.025%	cream
	Hydrocortisone probutate	0.1%	cream
	Hydrocortisone valerate	0.2%	cream
	Mometasone furoate	0.1%	cream, lotion, solution
	Prednicarbate	0.1%	ointment
Medium-High Potency (Group 3)	Amcinonide	0.1%	cream, lotion
	Betamethasone valerate	0.1%	ointment
	Diflorasone diacetate	0.05%	cream
	Fluocinonide	0.05%	cream
	Fluticasone propionate	0.005%	ointment
	Halcinonide	0.1%	ointment, solution
	Triamcinolone acetonide	0.5%	cream
	Triamcinolone acetonide	0.1%	ointment
High Potency (Group 2)	Amcinonide	0.1%	ointment
	Betamethasone dipropionate, augmented (Diprolene [®])	0.05%	cream, lotion
	Betamethasone dipropionate, unaugmented (Diprosone [®])	0.05%	cream, ointment
	Desoximetasone	0.25%	cream, ointment, spray
	Desoximetasone	0.05%	gel
	Diflorasone diacetate	0.05%	ointment
	Fluocinonide	0.05%	cream, gel, ointment, solution
	Halcinonide	0.1%	cream
	Mometasone furoate	0.1%	ointment
	Triamcinolone acetonide	0.5%	ointment
Super-High Potency (Group 1)	Betamethasone dipropionate, augmented (Diprolene [®])	0.05%	gel, ointment
	Clobetasol propionate	0.05%	cream, foam, gel, lotion, ointment, shampoo, spray

	Diflorasone diacetate	0.05%	ointment
	Fluocinonide	0.1%	cream
	Flurandrenolide	4 mcg/cm ²	tape
	Halobetasol propionate	0.05%	cream, ointment

Approval Criteria		
1. What diagnosis is being treated?	Record ICD 10 code.	
2. Is the request for treatment of severe inflammatory skin disease? Severe disease is defined as: ⁴ <ul style="list-style-type: none"> • Having functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on other validated tool) AND one or more of the following: <ol style="list-style-type: none"> 1. At least 10% body surface area involved OR 2. Hand, foot, face, or mucous membrane involvement 	Yes: Go to #4	No: If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP If eligible for EPSDT review: Go to #3
3. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)?	Yes: Go to #4	No: Pass to RPh. Deny; medical necessity
4. Is the diagnosis plaque psoriasis, atopic dermatitis or nonsegmental vitiligo?	Yes: Go to #5	No: Go to #8
5. Does the patient meet the age requirements per the FDA label? Note: minimum ages for commonly prescribed drugs are listed in Table 1	Yes: Go to #6	No: Pass to RPh. Deny; medical appropriateness
6. Is the requested product preferred?	Yes: Approve for 6 months	No: Go to #7

Approval Criteria

<p>7. Does the patient have a documented contraindication, intolerance or failed trials of at least 2 preferred first line agents (Table 2)?</p>	<p>Yes: Document drug and dates trialed, and intolerances or contraindications (if applicable): 1. _____ (dates) 2. _____ (dates)</p> <p>Approve for length of treatment; maximum 6 months.</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>8. Is the request for an FDA approved indication and age OR is supporting literature provided?</p>	<p>Yes: Approve for 1 year</p>	<p>No: Pass to RPh. Deny; medical appropriateness.</p>

*The Health Evidence Review Commission has stipulated via Guideline Note 21 that mild and moderate uncomplicated inflammatory skin conditions including psoriasis, atopic dermatitis, lichen planus, Darier disease, pityriasis rubra pilaris, and discoid lupus are not funded. Uncomplicated is defined as no functional impairment; and/or involving less than 10% of body surface area and no involvement of the hand, foot, or mucous membranes.

References:

1. Elmets 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;84(2):432-470.
2. Eleftheriadou, V., Atkar, R., Batchelor, J., McDonald, B., et al., British Association of Dermatologists guidelines for the management of people with vitiligo 2021*. *Br J Dermatol*, 186: 18-29. <https://doi.org/10.1111/bjd.20596>
3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at <http://www.micromedexsolutions.com>. Accessed October 6, 2022.
4. Oregon Health Evidence Review Commission. Coverage Guidance and Reports. <http://www.oregon.gov/oha/hpa/csi-herc/pages/index.aspx>. Accessed March 1, 2022.

P&T/DUR Review: 12/22 (DM); 6/22; 12/20; 10/20; 7/19; 5/19; 3/18; 9/17; 7/15; 1/15; 09/10; 9/09; 3/09; 5/07; 2/06
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