Clinical Policy: Topical Agents for Inflammatory Skin Disease

Reference Number: OR.CP.PMN.1009
Effective Date: 01.01.22
Last Review Date: 02.25
Line of Business: Medicaid – Trillium Oregon Health Plan Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Coverage guidelines for topical agents for treatment of inflammatory skin disease including: crisaborole (Eucrisa), pimecrolimus (Elidel), ruxolitinib (Opzelura), tacrolimus (Protopic), roflumilast (Zoryve), tapinarof (Vtama), calcipotriene (Sorilux, Dovonex), tazarotene (Tazorac), calcipotriene/betamethazone (Taclonex, Enstilar, Wynzora), anthralin (Zithranol), halobetasol propionate/tazarotene (Duobrii), calcitriol (Vectical).

These guidelines do not apply to oral or injectable targeted immune modulators for psoriasis or atopic dermatitis which are subject to separate clinical PA criteria.

Goals
- Restrict dermatological drugs only for funded Oregon Health Plan (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.

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.

Covered Alternatives:
- Current Trillium Preferred Drug List listed at: https://www.trilliumohp.com/providers/pharmacy.html

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Trillium Community Health Plan that the requested medication is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Psoriasis (must meet all)**:**

1. Member has a diagnosis of psoriasis;
2. Member meets one of the following (a, or b):
   a. Member is eligible for EPSDT review and was born in or after the year 2004;
   b. Condition is severe in nature as defined by 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 of the following (i or ii):
      i. At least 10% body surface area involved;
      ii. Hand, foot or mucous membrane involvement;
3. Failure of at least TWO first line agents (*see Appendix B*) unless clinically significant adverse effects are experienced or all are contraindicated;
4. Request is for a preferred product or member meets coverage guidelines in OR.CP.PMN.1001 for coverage of a non-preferred agent;
5. Member meets the age requirements per the FDA label (*see Appendix A*);

Approval duration: up to 12 months

B. Atopic Dermatitis (must meet all)**:**

1. Member has a diagnosis of atopic dermatitis;
2. Member meets one of the following (a, b, or c):
   a. Age <21 years;
   b. Member has Young Adults with Special Health Care Needs (YSHCN) coverage and was born in or after the year 2004;
   c. Condition is severe in nature as defined by 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 of the following (i or ii):
      i. At least 10% body surface area involved;
      ii. Hand, foot or mucous membrane involvement;
3. Failure of at least TWO first line agents (*see Appendix B*) unless clinically significant adverse effects are experienced or all are contraindicated;
4. Request is for a preferred product or member meets coverage guidelines in OR.CP.PMN.1001 for coverage of a non-preferred agent;
5. Member meets the age requirements per the FDA label (*see Appendix A*);

Approval duration: up to 6 months

C. Nonsegmental Vitiligo (must meet all)**:**

1. Member has a diagnosis of nonsegmental vitiligo;
2. Member meets one of the following (a, b, or c):
   a. Age <21 years;
   b. Member has Young Adults with Special Health Care Needs (YSHCN) coverage and was born in or after the year 2004;
   c. Condition is severe in nature as defined by 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 of the following (i or ii):
   i. At least 10% body surface area involved;
   ii. Hand, foot or mucous membrane involvement;
3. Failure of at least TWO first line agents (*see Appendix B*) unless clinically significant adverse effects are experienced or all are contraindicated;
4. Request is for a preferred product or member meets coverage guidelines in OR.CP.PMN.1001 for coverage of a non-preferred agent;
5. Member meets the age requirements per the FDA label (*see Appendix A*);

Approval duration: up to 12 months

D. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL the non-formulary policy for the relevant line of business: OR.CP.PMN.1001 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy

Approval duration: up to 12 months

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents

IV. Appendices/General Information

Appendix A: 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)

Generic Drug Name	Brand Name	Minimum Age	Indication (severity)
Pimecrolimus 1% ointment	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	ZORYVE	12 years	Plaque Psoriasis
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/Betamethazone ointment, suspension, foam Calcipotriene/Betamethazone 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

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

Appendix C: Potency of topical corticosteroid preparations using U.S. Classification

Potency Group	Corticosteroid	Strength	Formulation
Least Potency (Group 7)	Hydrocortisone Base and Hydrocortisone Acetate	0.5%, 1.0%, 2.0%	cream, ointment, gel, lotion, solution
	Alcometasone dipropionate	0.05%	cream, ointment

Low Potency (Group 6)	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 dipropionate	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

V. References

1. Topical Agents for Inflammatory Skin Disease. Oregon Health Plan Current Drug Use Criteria. Available at: http://orpdl.org/drugs/index.php. Accessed January 17, 2025.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 17, 2025.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from previously approved policy TCHP.PHAR.18004 Atopic Dermatitis and Topical Antipsoriatics. No clinically significant changes made.	09.21.21	10.21.21
2Q 2022 annual review: no significant changes; updated FDA approved ages in appendix B, references reviewed and updated.	03.17.22	04.07.22
2Q 2023 annual review: edited to mirror FFS coverage expansion for OHP members <21 years of age due to EPSDT waiver expiration; template changes applied to continued therapy section references reviewed and updated.	03.15.23	04.06.23
2Q 2024 annual review: no significant changes; references reviewed and updated.	04.01.24	05.21.24
Added standard YSHCN language to I.A., I.B. & I.C. for new 2025 OHP program coverage.	10.16.24	11.19.24
1Q 2025 annual review: no significant changes; references reviewed and updated.	01.17.25	02.11.25

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health

plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.