Policy: Acitretin (Soriatane)

Reference Number: OR.CP.PMN.40
Effective Date: 10.01.21
Last Review Date: 07.22
Line of Business: Medicaid - Oregon Health Plan

Revision Log

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

Description
Acitretin (Soriatane®) is an aromatic, synthetic retinoid.

FDA Approved Indication(s)
Soriatane is indicated for the treatment of severe psoriasis in adults.

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 Soriatane is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of psoriasis;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 18 years;
4. Member must meet one of the following (a or b):
   a. Failure of ≥ 8 week trial of phototherapy in combination with methotrexate or cyclosporine;
   b. If contraindication to methotrexate and cyclosporine, failure of ≥ 8 weeks of phototherapy in combination with one of the following agents: a medium to high potency steroid, tazarotene, or calcipotriene, unless contraindicated or clinically significant adverse effects are experienced;
   c. If phototherapy is not available, failure of two of the following from different classes, each used for ≥ 8 weeks at up to maximally indicated doses unless clinically significant adverse effects are experienced or all are contraindicated: a medium to high potency steroid, tazarotene, calcipotriene;
5. Member has severe inflammatory skin disease, defined as having functional impairment (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:
   a. At least 10% of body surfaces area involved
   b. Hand, foot or mucous membrane involvement

   *Guideline Note 21 of the Oregon Health Plan's Prioritized list is considered met if above requirement is met

6. Dose does not exceed 50 mg/day (2 capsules/day).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 50 mg/day (2 capsules/day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

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: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
methotrexate	10 to 25 mg orally/IV/IM as a single does weekly or 2.5 mg orally every 12 hours for 3 doses every week	30 mg/week
cyclosporine	1.25 mg/kg orally twice daily	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
tazarotene (Tazorac®)	Apply once daily	1 application daily
calcipotriene (Dovonex®)	Apply once or twice daily	100 g/week

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications

- Soriatane must not be used by females who are pregnant, or who intend to become pregnant during therapy or at any time for at least 3 years following discontinuation of therapy.
- Soriatane can cause hepatotoxicity, including abnormal liver function tests and inflammation of the liver.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Severe psoriasis	25 mg to 50 mg orally per day	50 mg per day

VI. Product Availability

Capsule: 10 mg, 17.5 mg, 25 mg

VII. References

1. Guideline 21 of the Oregon Health Plan's Prioritized List. http://lipaline.lipa.net. Accessed June 15, 2022.
2. Soriatane Prescribing Information. Research Triangle Park, NC: Stiefel Laboratories, Inc.; September 2017. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/019821s028lbl.pdf. Accessed May 12, 2022.
3. Acitretin Drug Monograph. Clinical Pharmacology. http://www.clinicalpharmacology-ip.com. Accessed June 15, 2022.
4. Menter A, Gordon KB, Connor C, et al. National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020 Feb;02.044

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from previously approved policy TCHP.PHAR.1802 Acitretin (Soriatane); requirements related to Guideline 21 updated; added path to approval when phototherapy is unavailable.	06.15.21	07.15.21
3Q 2022 annual review: no significant changes; references reviewed and updated	06.15.22	07.07.22

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.