Clinical Policy: Acitretin (Soriatane)

Reference Number: CP.PMN.40
Effective Date: 08.01.10
Last Review Date: 08.23
Line of Business: Medicaid

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 health plans affiliated with Centene Corporation® 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, b, or c):
   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, unless clinically significant adverse effects are experienced or all are contraindicated: a medium to high potency topical steroid, tazarotene, calcipotriene;
   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 topical steroid, tazarotene, calcipotriene;
5. Member must use generic acitretin, unless contraindicated or clinically significant adverse effects are experienced (e.g., contraindications to excipients);
6. Dose does not exceed both of the following (a and b):
   a. 50 mg per day;
   b. 2 capsules per day.

Approval duration:
Medicaid – 6 months

B. 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 formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 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. Psoriasis (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;
3. Member must use generic acitretin, unless contraindicated or clinically significant adverse effects are experienced (e.g., contraindications to excipients);
4. If request is for a dose increase, new dose does not exceed both of the following (a and b):
   a. 50 mg per day;
   b. 2 capsules per day.

Approval duration: 12 months

B. 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 formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 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.

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 PO/IV/IM as a single does weekly or 2.5 mg PO every 12 hours for 3 doses every week	30 mg/week
Topical corticosteroids	Varies	Varies
cyclosporine	1.25 mg/kg PO BID	Varies
tazarotene (Tazorac®)	Apply topically QD	1 application daily
calcipotriene (Dovonex®)	Apply topically QD or BID	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/Boxed Warnings

- Contraindication(s):
  - Pregnancy
  - Use in patients with severely impaired liver or kidney function and in patients with chronic abnormally elevated blood lipid values.
  - Combination use with methotrexate: an increased risk of hepatitis has been reported to result from combined use of methotrexate and etretinate. Note: Tegison (etretinate) is no longer marketed in the U.S.
  - Combination use with tetracyclines: may cause increased intracranial pressure.
  - Cases of hypersensitivity (e.g., angioedema, urticaria) to the preparation (acitretin or excipients) or to other retinoids.
- Boxed warning(s):
  - 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 should be considered only for women with severe psoriasis unresponsive to other therapies or whose clinical condition contraindicates the use of other treatments.
  - Hepatotoxicity.

V. Dosage and Administration

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

VI. Product Availability

Capsules: 10 mg, 17.5 mg, 25 mg

VII. References

1. Soriatane Prescribing Information. Research Triangle Park, NC: Stiefel Laboratories, Inc.; February 2023. Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process. Accessed April 27, 2023.
2. 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.
3. 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 Feb;84(2):432-470. doi: 10.1016/j.jaad.2020.07.087.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2019 annual review: no significant changes; references reviewed and updated.	05.21.19	08.19
3Q 2020 annual review: added rheumatologist as a prescriber option; references reviewed and updated.	04.29.20	08.20
3Q 2021 annual review: no significant changes; added legacy WellCare line of business with a separate approval duration (WCG.CP.PMN.40 to be retired); required use of generic formulation; references reviewed and updated.	04.02.21	08.21
3Q 2022 annual review: removed legacy Wellcare separate initial approval duration; references reviewed and updated.	05.12.22	08.22
Template changes applied to other diagnoses/indications and continued therapy section.	09.26.22	
3Q 2023 annual review: added “topical” to “medium to high potency steroid” in initial criteria to clarify and align with alternative agents listed in Appendix B; updated boxed warning section; references reviewed and updated.	04.27.23	08.23

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.