

Clinical Policy: Acitretin (Soriatane)

Reference Number: CP.PMN.40

Effective Date: 08.10

Last Review Date: 08.19

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;
3. Age \geq 18 years;
4. Member must meet one of the following (a, b, or c):
 - a. Failure of \geq 8 week trial of phototherapy in combination with methotrexate or cyclosporine;
 - b. If contraindication to methotrexate and cyclosporine, failure of \geq 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: a medium to high potency steroid, tazarotene, or calcipotriene each used for \geq 8 weeks at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 50 mg (2 capsules) per 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 (2 capsules) per 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 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.

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

Capsule: 10 mg, 17.5 mg, 25 mg

VII. References

1. Soriatane Prescribing Information. Research Triangle Park, NC: Stiefel Laboratories, Inc.; October 2018. Available at: https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Soriatane/pdf/SORIATANE-PI-MG.PDF. Accessed May 21, 2019.
2. Acitretin Drug Monograph. Clinical Pharmacology. <http://www.clinicalpharmacology-ip.com>. Accessed April 11, 2018.
3. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. *J Am Acad Dermatol*. 2009 Apr;60(4):643-59.
4. Menter A, Korman NJ, Elmets CA, Feldman SR, Gelfand JM, Gordon KB, Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011 Jul;65(1):137-74.
5. Menter A, Korman NJ, Elmets CA, Feldman SR, Gelfand JM, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 4. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. *J Am Acad Dermatol*. 2009 Sep;61(3):451-85.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|----------|-------------------|
| Converted to new template Added appropriate age of use to criteria Modified approval criteria to require use of two medium to high potency topical steroid each for ≥ 4 weeks or use of tazarotene or calcipotriene for ≥ 8 weeks; Added cyclosporine as an accepted preferred systemic first line agents that constitute an accepted trial; Modified criteria so that use of phototherapy with either a required topical agent or systemic agent is acceptable for approval Required monotherapy with phototherapy for at least 8 weeks in patients who are unable to use combination therapy | 08.15 | 08.15 |
| Updated template and references; Change diagnosis from chronic recalcitrant to psoriasis as the definition of severe is captured by the required agent that must be trialed; Removed requirement of Failure of two PDL medium to high potency steroids, each for ≥ 4 weeks, unless contraindicated OR Failure of ≥ 8 week trial of tazarotene or calcipotriene, unless contraindicated because that is the suggested treatment of mild to moderate psoriasis per uptodate and Menter et al; Removed requirement of “Do Your Part Program”; | 05.16 | 08.16 |
| Updated references | 03.17 | 08.17 |
| 3Q 2018 annual review: increased continued approved from 6 to 12 months; references reviewed and updated, added criteria when phototherapy is unavailable. | 04.11.18 | 08.18 |
| 3Q 2019 annual review: no significant changes; references reviewed and updated. | 05.21.19 | 08.19 |

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

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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.

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