Clinical Policy: Acitretin (Soriatane)
Reference Number: CP.PMN.40
Effective Date: 08/10
Last Review Date: 08/17
Line of Business: Medicaid

~~Coding Implications~~
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
Soriatane is indicated for the treatment of severe psoriasis in adults.

Policy/Criteria
Provider must submit documentation (~~including~~ which may include office chart notes and lab results) 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 ≥ 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 ~~C~~contraindication to methotrexate and cyclosporine, AND failure of ≥ 8 weeks of phototherapy in combination with any one of the following agents: a medium to high potency steroid, tazarotene, or calcipotriene, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 50 mg/day (2 capsules/day).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

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

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Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to CP.PMN~~XXX~~.53## if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

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 policy – CP.PMN.53 or evidence of coverage documents~~;~~

~~**B.** [Indications/diagnoses/situations in which drug is unsafe/ineffective] (This section should contain uses where the drug has been shown to be ineffective or unsafe or both. Do not list uses that are unproven, under investigation, or not studied here)~~

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
~~N/A~~FDA: Food and Drug Administration

Appendix B: Black Box Warning
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
S~~s~~evere psoriasis	25 mg to 50 mg per day	50 mg per day

VI. Product Availability

Capsule: 10 mg, 17.5 mg, 25 mg

VII. Workflow Document

Soriatane WF.docx

Field Code Changed

VIII. References

1. Acitretin Drug Monograph. Clinical Pharmacology. http://www.clinicalpharmacology-ip.com. Accessed March 2017.
2. Soriatane Package Insert. Research Triangle Park, NC: Stiefel Laboratories, Inc.; May 2015. Available at: http://www.soriatane.com/. Accessed March 2017.

~~3. 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 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. J Am Acad Dermatol. 2009 Apr;60(4):643-59. Feldman SR. Treatment of psoriasis. Dellavalle RD, Duffin KC. (Ed), UpToDate. Waltham MA. Accessed May 2016.~~

3.

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
References updated.	08/12	08/12
References updated.	08/14	08/15
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
~~Non-c~~Clinical changes to criteria Updated references	03/17	08/17

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Reviews, Revisions, and Approvals	Date	P&T Approval Date

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.

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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.