

## Clinical Policy: Acitretin (Soriatane)

Reference Number: PA.CP.PMN.40

Effective Date: 01/18

Last Review Date: 07/17/19

[Revision Log](#)

### Description

Acitretin (Soriatane<sup>®</sup>) 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 (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness<sup>®</sup> 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. Member must meet one of the following (a or b):
  - a. Failure of  $\geq 8$  week trial of phototherapy in combination with methotrexate or cyclosporine;
  - b. If contraindication to methotrexate and cyclosporine, AND failure of  $\geq 8$  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;
4. 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 Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (see PA.LTSS.PHAR.01) applies;
2. Documentation of positive response 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 Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (*see PA.LTSS.PHAR.01*) applies.

**Approval duration: Duration of request or 12 months (whichever is less);** or

2. Refer to CP.PMN.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

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

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
Severe psoriasis	25 mg to 50 mg per day	50 mg per day

**VI. Product Availability**

Capsule: 10 mg, 17.5 mg, 25 mg

**VII. References**

1. Acitretin Drug Monograph. Clinical Pharmacology. <http://www.clinicalpharmacology-ip.com>. Accessed April 11, 2018.
2. Soriatane Package Insert. Research Triangle Park, NC: Stiefel Laboratories, Inc.; October 2017. Available at: <http://www.soriatane.com/>. Accessed April 11, 2018.
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.
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
4Q 2018 annual review: no significant changes; increased continued approved from 6 to 12 months; references reviewed and updated.	08/18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	