# PRIOR AUTHORIZATION CRITERIA

**BRAND NAME***
**(generic)**

**SORIATANE**
**(acitretin)**

***Status: CVS Caremark Criteria***
***Type: Initial Prior Authorization*** ***Ref # 875-A***

** Drugs that are listed in the target drug box include both brand and generic and all dosages forms and strengths unless otherwise stated*

**FDA-APPROVED INDICATIONS**

Soriatane is indicated for the treatment of severe psoriasis in adults. Because of significant adverse effects associated with its use, Soriatane should be prescribed only by those knowledgeable in the systemic use of retinoids. In females of reproductive potential, Soriatane should be reserved for non-pregnant patients who are unresponsive to other therapies or whose clinical condition contraindicates the use of other treatments.

Most patients experience relapse of psoriasis after discontinuing therapy. Subsequent courses, when clinically indicated, have produced efficacy results similar to the initial course of therapy.

Compendial Use

- Prevention of non-melanoma skin cancers in high risk individuals[3,4]
- Lichen planus[3]
- Keratosis follicularis (Darier Disease)[3]

**COVERAGE CRITERIA**

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has a diagnosis of severe psoriasis OR lichen planus OR keratosis follicularis (Darier Disease)

**OR**

- The requested drug is being prescribed for the prevention of non-melanoma skin cancers in a high risk individual

**AND**

- If the patient is able to bear children then the patient and/or guardian signed a Patient Agreement/Informed Consent (e.g., Do Your P.A.R.T) which includes confirmation of 2 negative pregnancy tests

**RATIONALE**

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Soriatane is indicated for the treatment of severe psoriasis in adults. Only physicians knowledgeable in the use of retinoids and their significant adverse effects should prescribe Soriatane. In females of reproductive potential, Soriatane should only be prescribed for non-pregnant patients who are unresponsive to other therapies or whose clinical condition contraindicates the use of other treatments.

Due to the potential for birth defects, Soriatane should not be used in any female of reproductive potential until pregnancy has been excluded as confirmed by two negative urine or serum pregnancy tests with a sensitivity of at least 25 mIU/mL. To prevent fetal malformations, patients should use at least two effective forms of birth control. Birth control must be initiated at least one month before Soriatane use, during therapy, and at least three years after discontinuation of treatment. Elimination rates vary among patients and the duration of post therapy contraception to achieve adequate elimination cannot be calculated precisely. However, it is strongly recommended that contraception be continued for at least three years after stopping treatment with acitretin (Soriatane) in order for the drug to be eliminated to below a threshold blood concentration that would be associated with an increased incidence of birth defects. The patient must have a pregnancy test repeated every month during Soriatane treatment.

Ethanol use with Soriatane leads to the formation of etretinate, which has a significantly longer elimination half-life than acitretin (Soriatane). A longer half-life correlates to increased duration of teratogenic potential for female patients. Thus, ethanol must not be ingested by female patients either during treatment with Soriatane or for two months after cessation of therapy to allow for the elimination of acitretin (Soriatane), thus removing the substrate for transesterification to etretinate. Ethanol use with Soriatane in males may lead to a longer elimination half-life of the drug; however, this has not been established in the literature.[1,2,5]

A Patient Agreement/Informed Consent for Female Patients must be signed by the guardian of the patient or females of reproductive potential. This ensures the patient understands the risk of birth defects, the importance of avoiding pregnancy, and the dangers of alcohol use.

Based on available literature, oral retinoids (acitretin [Soriatane]) have been found to be effective in reducing the development of non-melanoma precancers and skin cancers in high-risk individuals.[4,5] Aggressive treatment or precancers can prevent the development of subsequent invasive tumors.[3] It has been well recognized that solid organ transplant recipients (ORTs) are at an increased risk of developing skin cancers. Data from a small number of randomized, controlled trials suggest that acitretin (Soriatane) may have a beneficial role in high-risk OTRs.[5]

According to the compendia and available literature, acitretin (Soriatane) therapy has been found to be an effective and acceptable therapy for severe cases of lichen planus. Acitretin produced remission or marked improvement in 64% of patients with lichen planus compared with 13% with placebo in an 8-week study and was associated with significant improvement in clinical symptoms of lichen planus during a 16-week study.[3,6,7]

According to available literature, acitretin (Soriatane) may be an alternative to etretinate (off market in the United States) for the treatment of Darier's disease (keratosis follicularis). Thirteen patients with Darier's disease were treated with acitretin (the main metabolite of etretinate) for 16 weeks.[3,8], Three patients were cleared completely, 7 patients showed marked improvement and 3 patients became slightly better during treatment. Despite good clearing, the improvement at the ultrastructural level was incomplete in the 3 patients studied by electron microscopy.[3,8] According to the National Organization of Rare Disorders (NORD), retinoids taken by mouth (orally) have been effective in treating individuals with keratosis follicularis and are the drugs most often used to treat severe cases.[9]

## REFERENCES


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**CRITERIA FOR APPROVAL**

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|---|---|---|---|
| 1 | Does the patient have the diagnosis of severe psoriasis OR lichen planus OR keratosis follicularis (Darier Disease)?<br>[If yes, then skip to question 3.] | Yes | No |
| 2 | Is the requested drug being prescribed for the prevention of non-melanoma skin cancers in a high risk individual? | Yes | No |
| 3 | Is the patient able to bear children?<br>[If no, then no further questions.] | Yes | No |
| 4 | Did the patient and/or guardian sign a Patient Agreement/Informed Consent (e.g., Do Your P.A.R.T) which includes confirmation of 2 negative pregnancy tests? | Yes | No |

| Mapping Instructions | | | |
|---|---|---|---|
| | **Yes** | **No** | **DENIAL REASONS – DO NOT USE FOR MEDICARE PART D** |
| 1. | Go to 3 | Go to 2 | |
| 2. | Go to 3 | Deny | Your plan covers this drug when you have one of these conditions:<br>- You have severe psoriasis<br>- You have lichen planus<br>- You have keratosis follicularis (Darier Disease)<br>- You require prevention of non-melanoma skin cancer<br>Your use of this drug does not meet the requirement. This is based on the information we have. |
| 3. | Go to 4 | Approve, 36 Months | |
| 4. | Approve, 36 Months | Deny | Your plan covers this drug when you meet all of these conditions:<br>- You and/or your guardian have signed a Patient Agreement/Informed Consent (e.g., Do Your P.A.R.T)<br>- You have 2 confirmed negative pregnancy tests<br>Your use of this drug does not meet the requirements. This is based on the information we have. |