Clinical Policy: Acitretin (Soriatane)

Reference Number: IN.CP.PMN.40
Effective Date: 01.01.2022
Last Review Date: 12.21
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.

I. Initial Approval Criteria

A. Must meet one of the following indications for treatment**:**

1. Hyperkeratotic dermatitis of the palms
2. Lichen planus
3. Palmoplantar pustulosis
4. Prophylaxis of skin cancer in high-risk kidney transplant recipients
5. Psoriasis classified as severe
6. Squamous cell carcinoma
7. Subcorneal pustular dermatosis (SPD; Sneddon-Wilkinson disease)

Approval duration:
Medicaid – 12 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. History of the requested agent within the past 90 days;

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

Capsules: 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 April 2, 2021.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: http://www.clinicalpharmacology-ip.com/. Accessed April 2, 2021.
3. 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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy Created to meet IN Medicaid Moratorium	12.2021	01.2022

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