PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

(acitretin)

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS

Acitretin Capsules are indicated for the treatment of severe psoriasis in adults. Because of significant adverse effects associated with its use, Acitretin Capsules should be prescribed only by those knowledgeable in the systemic use of retinoids. In females of reproductive potential, Acitretin Capsules 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 Uses
Prevention of non-melanoma skin cancers in high risk individuals[3,5]
Lichen planus[3]
Keratosis follicularis (Darier Disease)[3]

COVERAGE CRITERIA

Lichen Planus OR Keratosis Follicularis (Darier Disease)
Authorization may be granted when the requested drug is being prescribed for the treatment of Lichen Planus OR Keratosis follicularis (Darier Disease) when the following criteria is met:

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

Non-Melanoma Skin Cancers
Authorization may be granted when the requested drug is being prescribed for the prevention of non-melanoma skin cancers in a high-risk individual when the following criteria is met:

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

Severe Psoriasis
Authorization may be granted when the requested drug is being prescribed for the treatment of severe psoriasis when ALL of the following criteria are met:

- If the patient is able to bear children, then the patient and/or guardian signed a Patient Agreement/Informed Consent (e.g., T.A.P.P.) which includes confirmation of 2 negative pregnancy tests
- The patient has experienced an inadequate treatment response, intolerance, OR the patient has a contraindication to methotrexate OR cyclosporine

CONTINUATION OF THERAPY

Lichen Planus OR Keratosis Follicularis (Darier Disease)
Authorization may be granted when the requested drug is being prescribed for the treatment of Lichen Planus OR Keratosis follicularis (Darier Disease) when ALL of the following criteria are met:

- If the patient is able to bear children, then the patient and/or guardian signed a Patient Agreement/Informed Consent (e.g., T.A.P.P.) which includes confirmation of 2 negative pregnancy tests
- The patient has achieved or maintained a positive clinical response to the requested drug as evidenced by improvement

Non-Melanoma Skin Cancers
All patients (including new patients) requesting authorization for continuation of therapy must meet ALL requirements in the coverage criteria section.

Severe Psoriasis
Authorization may be granted when the requested drug is being prescribed for the treatment of severe psoriasis when ALL of the following criteria are met:

- If the patient is able to bear children, then the patient and/or guardian signed a Patient Agreement/Informed Consent (e.g., T.A.P.P.) which includes confirmation of 2 negative pregnancy tests
- The patient has achieved or maintained a positive clinical response to the requested drug as evidenced by improvement (e.g., clear, or almost clear outcome, patient satisfaction, etc.)

QUANTITY LIMITS APPLY
60 capsules per 25 days*†
**Acitretin must be dispensed in a one-month supply or less, there should be no 3-month supplies filled*
†The duration of 25 days is used for a 30-day fill period to allow time for refill processing.

DURATION OF APPROVAL (DOA)

- 875-C:
  - Severe Psoriasis, Lichen planus, Keratosis follicularis (Darier Disease): Initial therapy DOA: 6 months; Continuation of therapy DOA: 36 months
  - Prevention of non-melanoma skin cancers: DOA: 36 months
- 208-C:
  - Severe Psoriasis, Lichen planus, Keratosis follicularis (Darier Disease): Initial therapy DOA: 6 months; Continuation of therapy DOA: 12 months
  - Prevention of non-melanoma skin cancers: DOA: 12 months

REFERENCES

1. Acitretin [package insert]. Parsippany, NJ: Teva Pharmaceuticals; May 2022.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed May 29, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (*cited: 05/30/2024*).
4. Menter A, Gelfand J, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol* 2020;82:1444-86.
5. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology. Squamous Cell Skin Cancer. Version 1.2024. November 9, 2023. NCCN.org. Accessed May 30, 2024.
6. National Organization for Rare Disorders (NORD). Keratosis Follicularis. 2022. Available at https://rarediseases.org. Accessed May 30, 2024.