

PRIOR AUTHORIZATION POLICY

POLICY: Topical Acne – Winlevi Prior Authorization Policy

- Winlevi® (clascoterone 1% cream – Sun)

REVIEW DATE: 06/05/2024

OVERVIEW

Winlevi, an androgen receptor inhibitor, is indicated for the topical treatment of **acne vulgaris** in patients ≥ 12 years of age.¹

Safety

Winlevi is the only topical acne product with a Warning about hypothalamic-pituitary-adrenal (HPA) axis suppression.¹ This may result when Winlevi is used over large surface areas or if use is prolonged. In addition, pediatric patients may be more susceptible. This adverse event was not observed in the pivotal studies or in the long-term open-label extension study. However, it was observed in a small group of patients on Day 14 in a pharmacokinetic study. Normal HPA axis function was observed at follow-up at 4 weeks after end of treatment.

Guidelines

The most recent guidelines for management of acne from the American Academy of Dermatology was published in 2024.² Topical therapies, either as monotherapy or in combination with other topical agents or oral agents, are recommended for initial control and maintenance therapy of acne. Topical retinoids (tretinoin, adapalene, tazarotene) are the cornerstone of acne management due to their comedolytic and anti-inflammatory properties. Other topical therapies mentioned in the guidelines for management and treatment of acne include antibiotics (e.g., clindamycin, erythromycin), azelaic acid, dapsone, and salicylic acid. Winlevi was given a conditional recommendation for mild acne as part of a multimodal approach to treatment.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Winlevi. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Winlevi is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Acne Vulgaris.** Approve for 1 year if the patient meets the following (A, B, and C):

A) Patient is ≥ 12 years of age; AND

B) Patient has tried at least one prescription topical retinoid.

Note: Examples of a prescription topical retinoid are adapalene (Differin, generic), Aklief (trifarotene 0.005% cream), tazarotene 0.1% cream (Tazorac, generic), tazarotene 0.1% gel (Tazorac, generic), and tretinoin; AND

C) Patient has tried at least three other prescription non-retinoid topical therapies.

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Note: Topical retinoids do not count. Examples of other prescription non-retinoid topical therapies for acne include: dapsone gel (Aczone, generic), Azelex (azelaic acid 20% cream), topical clindamycin, topical erythromycin, and topical minocycline (Amzeeq [minocycline 4% foam]). For combination products, each active chemical entity counts as one trial. Example: If one prescription product has 2 non-retinoids, this would fulfill a trial of 2 non-retinoid topical therapies.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Winlevi is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Winlevi® cream [prescribing information]. Cranbury, NJ: Sun; July 2022.
2. Reynolds RV, Yeung H, Cheng CE, et al. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol.* 2024;90(5):1006.e1-1006.e30.