

PRIOR AUTHORIZATION POLICY

POLICY: Topical Acne – Winlevi Prior Authorization Policy

- Winlevi® (clascoterone cream 1% – Cassiopea Inc)

REVIEW DATE: 12/16/2020

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

Winlevi has not been added to the American Academy of Dermatology guidelines for the management of acne (2016).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 are the cornerstone of acne management due to their comedolytic and anti-inflammatory properties.

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 criteria (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, Akliet® [trifarotene cream 0.005%], tazarotene (Tazorac® 0.1% cream [generics], Tazorac 0.1% gel), and tretinoin; AND

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

Note: Examples of other prescription topical therapies for acne include: Aczone® (dapsone gel 7.5%; dapsone gel 5% [generics]), Azelex® (azelaic acid cream 20%), topical clindamycin, topical erythromycin, and topical minocycline (Amzeeq™ [minocycline foam 4%]).

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]. San Diego, CA: Cassiopea Inc; August 2020.
2. Zaenglein AL, Pathy AL, Schlosser BJ, et al. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol*. 2016;74:945-73.

HISTORY

Type of Revision	Summary of Changes	Review Date
New policy	--	12/16/2020