

Drug Policy

Policy:	Winlevi (clascoterone cream 1%)	Annual Review Date: 03/20/2025 Last Revised Date: 03/20/2025
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OVERVIEW

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

POLICY STATEMENT

This policy involves the use of Winlevi. Prior authorization is recommended for pharmacy benefit coverage of Winlevi. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals are provided for the approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. **Acne Vulgaris**

Criteria. *Patient must meet 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 (Differin, generic), Akliel® [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 non-retinoid topical therapies.
Note: Topical retinoids do not count. Examples of other prescription non-retinoid topical therapies for acne include: Aczone® (dapson gel 7.5%; dapson gel 5% [generics]), Azelex® (azelaic acid cream 20%), topical clindamycin, topical erythromycin, and topical minocycline (Amzeeq™ [minocycline foam 4%]). 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.

Initial Approval/ Extended Approval.

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A) Initial Approval: 365 days

B) Extended Approval: 365 days

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Winlevi has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company.

Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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.