

Policy Name:	Winlevi (clascoterone)	Policy#:	2829P
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Purpose of the Policy

The purpose of this policy is to define coverage criteria for Winlevi (clascoterone) for the treatment of acne.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Winlevi (clascoterone) under the pharmacy benefit if the following criteria are met.

Criteria

1. Coverage Criteria for Acne Vulgaris

- 1.1 Documented diagnosis of acne vulgaris
- 1.2 Documented trial and failure of at least two formulary generic agents (e.g., topical agents such as tretinoin, adapalene, or oral tetracyclines) or documented contraindication to all topical agents and oral tetracyclines

2. Exclusion Criteria

- 2.1 Previous history of hypothalamic-pituitary-adrenal (HPA) axis suppression

3. Approval Period

- 3.1 Initial Approval: 12 months
- 3.2 Subsequent Approvals: 12 months with positive response to therapy

CPT Codes

HCPCS Codes

References

1. Winlevi (clascoterone) [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries Inc; December 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):1006-30.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.