

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2241-5
Program	Prior Authorization/Medical Necessity
Medications	Winlevi® (clascoterone)
P&T Approval Date	6/2021, 6/2022, 7/2023, 7/2024, 9/2025
Effective Date	11/16/2025

1. Background:

Winlevi (clascoterone) is an androgen receptor inhibitor indicated for the topical treatment of acne vulgaris in patients 12 years of age and older. Guidelines from the American Academy of Dermatology recommend topical therapies for mild acne including retinoids, benzoyl peroxide, topical antibiotics in combination with benzoyl peroxide or topical retinoid with a strong recommendation. Clascoterone, salicylic acid and azelaic acid have conditional recommendations.

2. Coverage Criteria^a:**A. Initial Authorization**

1. **Winlevi*** will be approved based on **all** of the following criteria:

- a. Diagnosis of acne vulgaris

-AND-

- b. Patient is 12 years of age or older

-AND-

- c. History of failure, contraindication, or intolerance to an adequate trial of a topical retinoid [(e.g. tretinoin (generic Retin-A))]

-AND-

- d. History of failure, contraindication, or intolerance to an adequate trial of a topical antibiotic in combination with benzoyl peroxide [e.g., benzoyl peroxide/clindamycin (generic Duac), benzoyl peroxide/erythromycin (generic Benzamycin)]

-AND-

- e. History of failure, contraindication, or intolerance to an adequate trial of a topical dapsone (e.g. generic Aczone).

Authorization will be issued for 6 months.

B. Reauthorization

1. **Winlevi*** will be approved based on the following criteria:

- a. Documentation of positive clinical response to therapy

-AND-

- b. Patient has been assessed for signs of hypothalamus-pituitary-adrenal (HPA) axis suppression (e.g. fatigue, weight loss, abdominal pain, depression, muscle weakness)

Reauthorization will be issued for 6 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. **Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits may be in place.
*Typically excluded from coverage.

4. **References:**

1. Winlevi [package insert]. Cranbury NJ: Sun Pharmaceuticals Industries, Inc; July 2022.
2. Reynolds, Rachel V. et al. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol* 2024;90:1006.e1-30

Program	Prior Authorization/Medical Necessity - Winlevi
Change Control	
Date	Change
6/2021	New program
6/2022	Annual review. Updated references.
7/2023	Annual review. Updated example to generic. Updated references.
7/2024	Annual review. Updated references.
9/2025	Annual review with no changes.