

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 2241-1
Program	Prior Authorization/Medical Necessity
Medications	Winlevi (clascoterone)
P&T Approval Date	6/2021
Effective Date	9/1/2021; Oxford only: 9/1/2021

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 including retinoids, antibiotics in combination with benzoyl peroxide, azelaic acid and dapsone for mild to moderate acne. Systemic antibiotics are first-line in moderate to severe acne with concomitant topical therapy of benzoyl peroxide or a retinoid.

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. 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.

4. References:

1. Winlevi [package insert]. Milan, Italy: Cassiopea, Inc; August 2020.
2. Zaenglein, Andrea L. et al. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol.* May 2016;74(5):945–973.e33

Program	Prior Authorization/Medical Necessity - Winlevi
Change Control	
Date	Change
6/2021	New program