

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	July 1, 2025

Winlevi® (clascoterone)

LENGTH OF AUTHORIZATION: 1 year

REVIEW CRITERIA:

- Patient must be ≥ 12 years of age; **AND**
- Patient must have a diagnosis of acne vulgaris; **AND**
- Patient had an inadequate response, intolerance, or contraindication to the following preferred therapeutic alternatives (clinical documentation demonstrating failure to previous therapies must be provided):
 - Topical antibiotics (i.e., clindamycin, clindamycin-benzoyl peroxide, erythromycin-benzoyl peroxide); **AND;**
 - Adapalene-benzoyl peroxide; **AND**
 - Retin-A cream.

CONTINUATION OF THERAPY:

- Patient met initial review criteria; **AND**
- Documentation of improved clinical response; **AND**
- Patient has not experienced any treatment-restricting adverse effects; **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>
- Available as a 1% cream.