



Winlevi (clascoterone) Step Therapy Program Summary

FDA APPROVED INDICATIONS AND DOSAGE¹

Agent(s)	Indication(s)	Dosage
Winlevi® (clascoterone) Cream	Indicated for the topical treatment of acne vulgaris in patients 12 years of age and older	Apply a thin layer twice daily to the affected areas

CLINICAL RATIONALE

Acne Vulgaris

The American Academy of Dermatology suggests several options for treatment of acne vulgaris in adolescents and young adults. Recommendations for topical acne therapies include benzoyl peroxide or combination with topical antibiotics (e.g. erythromycin or clindamycin) as monotherapy for mild acne, or in conjunction with topical retinoid, or systemic antibiotic therapy for moderate to severe acne. Topical antibiotics are not recommended as monotherapy due to risk of bacterial resistance, and due to increased efficacy when used in combination with benzoyl peroxide. Clindamycin 1% solution or gel is currently the preferred topical antibiotic for acne therapy. Erythromycin 2% available in multiple formulations but has reduced efficacy compared to clindamycin due to resistance of cutaneous Staphylococci and P acnes.²

Topical adapalene, tretinoin, and benzoyl peroxide can be safely used in the management of preadolescent acne in children. Azelaic acid is useful as an adjunctive acne treatment and is recommended in the treatment of post-inflammatory dyspigmentation. Topical dapsone 5% gel is recommended for inflammatory acne, particularly in adult females with acne. There is limited data to support sulfur, nicotinamide, resorcinol, sodium sulfacetamide, aluminum chloride, and zinc in the treatment of acne.² If topical antibiotic treatment is to be prolonged for more than a few weeks, topical benzoyl peroxide should be added, or used in combination products.³ Topical androgen receptor inhibitors, such as Winlevi, are not addressed in guidelines at this time and do not have a place in therapy.

REFERENCES

1. Winlevi prescribing information. Cassiopea, Inc. August 2020.
2. Zaenglein, Andrew L. MD, et al. American Academy of Dermatology. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol*. 2016;74:945-73.
3. Eichenfield L, Krakowski A, Piggott C, et al. Evidence-based recommendations for the diagnosis and treatment of pediatric acne. *Pediatrics*. 2013;131;S163-S186.

Winlevi (clascoterone) Step Therapy

TARGET AGENT(S)

Winlevi® (clascoterone)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Target Agent(s) will be approved when BOTH of the following are met:

1. ONE of the following:
 - A. The requested agent is eligible for continuation of therapy AND ONE of the following:
 - i. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days
OR
 - ii. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed

Agent(s) Eligible for Continuation of Therapy

Winlevi

OR

- B. ONE of the following:
 - i. The patient's medication history includes use of at least ONE generic topical antibiotic agent OR at least ONE generic topical retinoid agent within the past 90 days
OR
 - ii. The patient has an intolerance or hypersensitivity to generic topical antibiotic OR generic topical retinoid therapy
OR
 - iii. The patient has an FDA labeled contraindication to ALL generic topical antibiotic AND generic topical retinoid agents

AND

2. ONE of the following:
 - A. The patient is 12 years of age or over
OR
 - B. The prescriber has provided information in support of using the requested agent for the patient's age

Length of Approval: 12 months