

Initial Prior Authorization

Winlevi

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Winlevi	clascoterone	cream

Indications

FDA-approved Indications

Winlevi (clascoterone) cream is an androgen receptor inhibitor indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

Coverage Criteria

Acne Vulgaris

Authorization may be granted when the requested drug is being prescribed for the topical treatment of acne vulgaris

Continuation of Therapy

Acne Vulgaris

Authorization may be granted when the requested drug is being prescribed for the topical treatment of acne vulgaris when the following criteria is met:

- The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., reduction in number of lesions, patient satisfaction, etc.)

Duration of Approval (DOA)

- 4265-A: Initial therapy DOA: 4 months; Continuation of therapy DOA: 12 months

References

1. Winlevi (clascoterone) cream [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; July 2022.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed July 1, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 07/01/2024).
4. 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.e1-1006.e30.
5. Hebert A, Thiboutot D, Stein Gold L, et al. Efficacy and safety of topical clascoterone cream, 1%, for treatment in patients with facial acne: two phase 3 randomized clinical trials. JAMA Dermatol. 2020;156(6):621.