

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

WINLEVI
(clascoterone cream)

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization

POLICY

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

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the topical treatment of acne vulgaris
AND
 - The request is NOT for continuation of therapy**OR**
 - The request is for continuation of therapy
AND
 - The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., reduction in number of lesions, 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.; 2023. <https://online.lexi.com>. Accessed June 12, 2023.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 06/12/2023).
4. Zaenglein AL, Pathy AL, Schlosser BJ, et al. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol*. 2016;74(5):945-973.
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.

Winlevi PA Policy 4265-A UDR 08-2023.docx

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