

# 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

Winlevi PA 4265-A P08-2024\_R.docx

© 2024 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

# **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<sup>®</sup> (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.

Winlevi PA 4265-A P08-2024\_R.docx

© 2024 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.