

Clinical Policy Title:	clascoterone
Policy Number:	RxA.798
Drug(s) Applied:	Winlevi®
Original Policy Date:	04/13/2023
Last Review Date:	01/01/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Acne Vulgaris (must meet all):

1. Diagnosis of acne vulgaris;
2. Trial and failure of ≥ 2 of the following topical preparations, each from different medication classes, each used for ≥ 2 months, unless clinically significant adverse effects are experienced or all are contraindicated:
 - a. Topical antibiotics: clindamycin, erythromycin;
 - b. Topical anti-infectives: benzoyl peroxide;
 - c. Topical retinoids: tretinoin, tazarotene, adapalene;

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Acne Vulgaris (must meet all):

1. Member is currently receiving medication, excluding manufacturer samples;

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Zaenglein AL, Pathy AL, Schlosser BJ, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol 2016;74:945-73. Available at: <https://pubmed.ncbi.nlm.nih.gov/26897386/>. Accessed December 18, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	04/06/2023	04/13/2023
Policy was reviewed: <ol style="list-style-type: none"> 1. Removed prior age criteria. 2. Removed prior dosing criteria. 3. Updated approval duration. 4. Removed reauthorization requirement for positive response to therapy. 5. References were reviewed and updated. 	12/18/2023	01/01/2024

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