

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

Background

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

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Clascoterone (Winlevi®)	Acne Vulgaris	Apply (approximately 1 gram) to affected area twice daily (morning and evening).	2 gm/day

Dosage Forms

- Cream 1% (60 gm tube)

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Acne Vulgaris (must meet all):

1. Diagnosis of acne vulgaris;
2. Age \geq 12 years;
3. Trial and failure of \geq 2 of the following topical preparations, each from different medication classes, each used for \geq 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;
4. Dose does not exceed 60 gm per month.

Approval Duration

Commercial: 12 months

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Medicaid: 12 months

II. Continued Therapy Approval

A. Acne Vulgaris (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 60 gm per month.

Approval Duration

Commercial: 12 months

Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

HPA: Hypothalamic-pituitary-adrenal

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
clindamycin (Cleocin T®)	Apply a thin film twice daily	twice daily
erythromycin (Erygel®)	Apply a thin film twice daily	twice daily
benzoyl peroxide (BPO®, PanOxyl®)	Apply or wash once daily or twice daily	twice daily
tretinoin (Retin-A®)	Apply a thin layer to the affected area(s) once daily at bedtime	Various
Tazarotene (Tazorac®)	Apply a thin layer to the affected area(s) once daily at bedtime	Various
adapalene (Differin®)	Apply a thin layer to the affected area(s) once daily at bedtime	Various

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
 - None reported.
- Boxed Warning(s):
 - None reported.

APPENDIX D: General Information

- Hypothalamic-pituitary-adrenal (HPA) axis suppression may occur during or after treatment with clascoterone.
- Hyperkalemia: Elevated potassium levels were observed in some subjects during the clinical trials.

References

1. Winlevi® Prescribing Information. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; July 2022. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=1673a84b-7f5c-47ab-a99c-1e3db21a6a09&type=display>. Accessed April 06, 2023.
2. 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 April 06, 2023.
3. Clinical Pharmacology. Tampa, FL: Elsevier, 2023. Available at: <https://www.clinicalkey.com>. Accessed April 06, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	04/06/2023	04/13/2023