

Clinical Policy: Clascoterone (Winlevi)

Reference Number: CP.PMN.257

Effective Date: 03.01.21

Last Review Date: 02.25

Line of Business: Commercial, HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Clascoterone (Winlevi[®]) is an androgen receptor inhibitor.

FDA Approved Indication(s)

Winlevi is indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that Winlevi is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Acne Vulgaris (must meet all):

1. Diagnosis of acne vulgaris;
2. Age \geq 12 years;
3. Failure of \geq 2 of the following generic formulary 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;

**Prior authorization may be required for tretinoin*
4. Dose does not exceed 60 grams (1 tube) per month.

Approval duration:

Medicaid/HIM – 12 months

Commercial – 12 months or duration of request, whichever is less

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business:

- CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
- b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Acne Vulgaris (must meet all):

1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 60 grams (1 tube) per month.

Approval duration:

Medicaid/HIM – 12 months

Commercial –12 months or duration of request, whichever is less

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
clindamycin (Cleocin T [®])	Apply a thin film BID	BID
erythromycin (Erygel [®] , Ery [®])	Apply a thin film BID	BID
benzoyl peroxide (Benzac [®] , BPO [®] , Brevoxyl [®] , PanOxyl [®])	Apply or wash 1 to 3 times daily	TID
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 Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Acne vulgaris	Apply approximately 1 gram topically to the affected area twice daily	2 gm/day

VI. Product Availability

Cream: 1% (60 g tube)

VII. References

1. Winlevi Prescribing Information. San Diego, CA: Cassiopea Inc.; March 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/213433Orig1s0021bl.pdf. Accessed October 22, 2024.
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.

3. Reynolds RV, Yeung H, Cheng CE, et al. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol.* 2024 May;90(5):1006.e1-1006.e30. doi: 10.1016/j.jaad.2023.12.017.
4. *Clinical Pharmacology* [database online]. Tampa, FL: Gold Standard, Inc.; 2024. Available at: <https://www.clinicalkey.com/pharmacology/>. Accessed October 31, 2024.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created; references to HIM.PHAR.21 revised to HIM.PA.154.	09.22.20	02.21
1Q 2022 annual review: no significant changes; added generic tazarotene as an option; references reviewed and updated.	10.01.21	02.22
Revised approval duration for Commercial line of business from length of benefit to 12 months or duration of request, whichever is less.	04.27.22	08.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.06.22	
1Q 2023 annual review: no significant changes; added generic adapalene as an option; updated dosing for retinoid alternatives in Appendix B to align with other retinoid policies; references reviewed and updated.	11.03.22	02.23
1Q 2024 annual review: for initial approval criteria, updated “failure of ≥ 2 of the following topical preparations” to “failure of ≥ 2 of the following generic formulary topical preparations”; updated dosing for benzoyl peroxide in Appendix B; references reviewed and updated. In initial approval criteria, added clarification stating prior authorization may be required for tretinoin.	02.13.24	02.24
1Q 2025 annual review: no significant changes; references reviewed and updated.	10.22.24	02.25

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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