Drug Coverage Policy

Effective Date.....8/1/2025
Coverage Policy Number IP0173
Policy Title.....Winlevi

Topical Acne – Winlevi

- Winlevi® (clascoterone 1% cream – Sun)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

Winlevi, an androgen receptor inhibitor, is indicated for the topical treatment of **acne vulgaris** in patients ≥ 12 years of age.[1]

Guidelines
Guidelines for the management of acne vulgaris from the American Academy of Dermatology (2024) recommend multimodal therapy combining multiple mechanisms of action when managing acne with topical medications.[2] Strong recommendations are made for topical benzoyl peroxide, retinoids, antibiotics and combinations products (i.e. topical antibiotic + benzoyl peroxide; topical retinoid + benzoyl peroxide, topical retinoid + topical antibiotic). Conditional recommendations are made for topical clascoterone, salicylic acid, and azelaic acid.

Coverage Policy

Policy Statement

Prior Authorization is required for benefit coverage of Winlevi. All approvals are provided for the duration noted below.

Winlevi is considered medically necessary when the following criteria are met:

FDA-Approved Indication

1. **Acne Vulgaris.** Approve for 1 year if the patient meets the following (A, B, and C):
   - **A)** Patient is ≥ 12 years of age; AND
   - **B)** Patient has tried at least one prescription topical retinoid for the treatment of acne vulgaris; AND
     Note: Examples of prescription topical retinoidsinclude adapalene (Differin, generic), Aklief (trifarotene 0.005% cream), Arazlo (tazarotene 0.045% lotion), Fabior (tazarotene 0.1% foam), tazarotene 0.1% cream and gel (Tazorac, generic) ,tretinoin.
   - **C)** Patient has tried at least three other prescription non-retinoid topical therapies for the treatment of acne vulgaris.
     Note: Topical retinoids do not count. Examples of other prescription non-retinoid topical therapies for acne include: benzoyl peroxide, dapsone gel (Aczone, generic), Azelex (azelaic acid 20% cream), topical clindamycin, topical erythromycin, topical minocycline (Amzeeq [minocycline 4% foam]). For combination products, each active chemical entity counts as one trial. Example: If one topical prescription product has 2 non-retinoids, this would fulfill a trial of 2 non-retinoid topical therapies.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Winlevi for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

References

1. Winlevi® cream [prescribing information]. Cranbury, NJ: Sun; January 2025.
2. 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.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	No criteria change.	4/15/2024
Selected Revision	**Acne Vulgaris.** Criterion that "Documentation of failure, contraindication, or intolerance to at least three other prescription topical therapies" was clarified that these are non-retinoid therapies; the new criterion reads: "Documentation patient has tried at least three other prescription non-retinoid topical therapies."	6/1/2024
Early Annual Revision	**Acne Vulgaris. Added** *notes* under the criteria for trials with topical retinoids and topical non-retinoids with examples of products to satisfy criteria. **Removed** *documentation* language from criteria. **Removed** *Reauthorization Criteria*.	9/15/2024
Annual Revision	**Acne Vulgaris**: The requirement for previous trials of prescription medications was updated to add "for the treatment of acne vulgaris" throughout the Policy. The Note providing examples of prescription topical retinoids was updated to add Arazlo (tazarotene 0.045% lotion) and Fabior (tazarotene 0.1% foam). The Note providing examples of prescription non-retinoid topical therapies was updated to include benzoyl peroxide.	8/1/2025

The policy effective date is in force until updated or retired.

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