Drug Coverage Policy

Effective Date.....9/15/2024
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 and have discretion in making individual coverage determinations. 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.

Cigna Healthcare Coverage Policy

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

Safety
Winlevi is the only topical acne product with a Warning about hypothalamic-pituitary-adrenal (HPA) axis suppression.[1] This may result when Winlevi is used over large surface areas or if use is prolonged. In addition, pediatric patients may be more susceptible. This adverse event was not

observed in the pivotal studies or in the long-term open-label extension study. However, it was observed in a small group of patients on Day 14 in a pharmacokinetic study. Normal HPA axis function was observed at follow-up at 4 weeks after end of treatment.

Guidelines
The most recent guidelines for management of acne from the American Academy of Dermatology was published in 2024.[2] Topical therapies, either as monotherapy or in combination with other topical agents or oral agents, are recommended for initial control and maintenance therapy of acne. Topical retinoids (tretinoin, adapalene, tazarotene) are the cornerstone of acne management due to their comedolytic and anti-inflammatory properties. Other topical therapies mentioned in the guidelines for management and treatment of acne include antibiotics (e.g., clindamycin, erythromycin), azelaic acid, dapsone, and salicylic acid. Winlevi was given a conditional recommendation for mild acne as part of a multimodal approach to treatment.

Medical Necessity Criteria

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.
     Note: Examples of a prescription topical retinoid are adapalene (Differin, generic), Aklief (trifarotene 0.005% cream), tazarotene 0.1% cream (Tazorac, generic), tazarotene 0.1% gel (Tazorac, generic), and tretinoin; AND
   - **C)** Patient has tried at least three other prescription non-retinoid topical therapies.
     Note: Topical retinoids do not count. Examples of other prescription non-retinoid topical therapies for acne include: dapsone gel (Aczone, generic), Azelex (azelaic acid 20% cream), topical clindamycin, topical erythromycin, and topical minocycline (Amzeeq [minocycline 4% foam]). For combination products, each active chemical entity counts as one trial. Example: If one 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

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

References

1. Winlevi® cream [prescribing information]. Cranbury, NJ: Sun; July 2022.
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

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