



Drug Coverage Policy

Effective Date4/15/2024
Coverage Policy Number.....IP0173

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.

Medical Necessity Criteria

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

1. **Acne Vulgaris.** Individual meets **ALL** of the following criteria:
 - A. Age 12 years or older
 - B. Documentation of failure, contraindication, or intolerance to at least **ONE** prescription topical retinoid [may require prior authorization]
 - C. Documentation of failure, contraindication, or intolerance to at least **THREE** other prescription topical therapies for acne

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.

Reauthorization Criteria

Continuation of clascoterone (Winlevi) is considered medically necessary for the treatment of acne vulgaris when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months

Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered not medically necessary.

Background

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 2016, before the approval of Winlevi.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.

References

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

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	No criteria changes	4/15/2024

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

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