



PRIOR AUTHORIZATION POLICY

POLICY: Topical Acne – Winlevi Prior Authorization Policy

- Winlevi® (clascoterone 1% cream – Sun)

REVIEW DATE: 12/20/2023, selected revision 02/28/2024

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 NATIONAL FORMULARY COVERAGE:

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.

POLICY STATEMENT

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

- **Winlevi® (clascoterone 1% cream – Sun)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. Acne Vulgaris. Approve for 1 year if the patient meets the following (A, B, and C):

A) Patient is \geq 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), Akliel (trifarotene 0.005% cream), tazarotene 0.1% cream (Tazorac, generic), taxarotene 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]).

CONDITIONS NOT COVERED

- **Winlevi® (clascoterone 1% cream – Sun)**

is(are) considered experimental, investigational, or unproven for ANY other use(s).

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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria change.	12/14/2022
Annual Revision	No criteria change.	12/20/2023
Selected Revision	Acne Vulgaris. Criterion that "Patient has tried three other prescription topical therapies" was clarified that these are non-retinoid therapies; the new criterion reads: Patient	2/28/2024

	has tried at least three other prescription non-retinoid topical therapies. "Topical retinoids do not count" was added to the Note.	
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