

5.90.047

Section:	Prescription Drugs	Effective Date:	October 1, 2023
Subsection:	Topical Products	Original Policy Date:	January 29, 2021
Subject:	Winlevi	Page:	1 of 4

Last Review Date: September 8, 2023

Winlevi

Description

Winlevi (clascoterone)

Background

Winlevi (clascoterone) is an androgen receptor inhibitor. The mechanism of action of Winlevi cream for the topical treatment of acne vulgaris is unknown (1).

Regulatory Status

FDA-approved indication: Winlevi (clascoterone) cream is an androgen receptor inhibitor indicated for the topical treatment of acne vulgaris in patients 12 years of age and older (1).

The safety and effectiveness of Winlevi in pediatric patients less than 12 years of age have not been established (1).

Related policies

Aczone, Tretinoin, Tazarotene

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Winlevi may be considered **medically necessary** if the conditions indicated below are met.

Winlevi may be considered **investigational** for all other indications.

Section:	Prescription Drugs	Effective Date:	October 1, 2023
Subsection:	Topical Products	Original Policy Date:	January 29, 2021
Subject:	Winlevi	Page:	2 of 4

Prior-Approval Requirements

Age 12 years of age or older

Diagnosis

Patient must have the following:

1. Acne vulgaris
 - a. Comedones
 - b. Cysts (eruptive vellus hair cyst, cystic acne)
 - c. Papules
 - d. Pustules

AND the following:

1. Patient has had an inadequate response, intolerance, or contraindication to **TWO** topical generic acne products including at least one of each of the following:
 - a. Topical antibiotic
 - b. Topical retinoid

Prior-Approval *Renewal* Requirements

Age 12 years of age or older

Diagnosis

Patient must have the following:

1. Acne vulgaris
 - a. Comedones
 - b. Cysts (eruptive vellus hair cyst, cystic acne)
 - c. Papules
 - d. Pustules

Section:	Prescription Drugs	Effective Date:	October 1, 2023
Subsection:	Topical Products	Original Policy Date:	January 29, 2021
Subject:	Winlevi	Page:	3 of 4

Policy Guidelines

Pre-PA Allowance

None

Prior-Approval Limits

Quantity

Drug	Quantity
Winlevi 1% cream	360 units per 90 days

Duration 12 months

Prior-Approval *Renewal* Limits

Same as above

Rationale

Summary

Winlevi (clascoterone) is an androgen receptor inhibitor. The mechanism of action of Winlevi cream for the topical treatment of acne vulgaris is unknown (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Winlevi while maintaining optimal therapeutic outcomes.

References

1. Winlevi [package insert]. Milan, Italy: Cassiopea, Inc.; September 2021.

Policy History

Date	Action
January 2021	Addition to PA
May 2021	Annual review

5.90.047

Section:	Prescription Drugs	Effective Date:	October 1, 2023
Subsection:	Topical Products	Original Policy Date:	January 29, 2021
Subject:	Winlevi	Page:	4 of 4

July 2021	Changed requirement from “t/f one topical generic acne product” to “t/f two topical generic acne products, including a topical retinoid and a topical antibiotic” per FEP
September 2021	Annual review
December 2021	Annual review
June 2022	Annual review and reference update
September 2023	Annual editorial review. Changed policy number to 5.90.047

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 8, 2023 and is effective on October 1, 2023.