

5.90.47

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

Last Review Date: March 12, 2021

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

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** for patients 12 years and older for acne vulgaris and if the conditions below are met.

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

Winlevi may be considered **investigational** in patients less than 12 years of age and for all other indications.

Prior-Approval Requirements

Age 12 years of age

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 a topical generic acne product (e.g., benzoyl peroxide, topical antibiotics, topical retinoid, or any combination)

Prior-Approval *Renewal* Requirements

Age 12 years of age

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:	April 1, 2021
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.; August 2020.

Policy History

Date	Action
January 2021	Addition to PA
May 2021	Annual review

5.90.47

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.