

5.90.47

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	July 1, 2022
<b>Subsection:</b>	Topical Products	<b>Original Policy Date:</b>	January 29, 2021
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**Last Review Date:** June 16, 2022

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## Winlevi

### Description

Winlevi (clascoterone)

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### 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).

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

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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 **TWO** topical generic acne products including at least one of each of the following:
  - a. Topical antibiotic
  - b. Topical retinoid

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## Prior-Approval *Renewal* Requirements

**Age** 12 years of age

### Diagnosis

Patient must have the following:

1. Acne vulgaris

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

### Policy Guidelines

#### Pre-PA Allowance

None

#### Prior-Approval Limits

##### Quantity

Drug	Quantity
Winlevi 1% cream	360 units per 90 days

**Duration** 12 months

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#### 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

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Date	Action
January 2021	Addition to PA
May 2021	Annual review
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

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.**