
5.90.047

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|--------------------|--------------------|------------------------------|------------------|
| Section: | Prescription Drugs | Effective Date: | October 1, 2024 |
| Subsection: | Topical Products | Original Policy Date: | January 29, 2021 |
| Subject: | Winlevi | Page: | 1 of 4 |

Last Review Date: September 6, 2024

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.

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|--------------------|--------------------|------------------------------|------------------|
| Section: | Prescription Drugs | Effective Date: | October 1, 2024 |
| 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

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|--------------------|--------------------|------------------------------|------------------|
| Section: | Prescription Drugs | Effective Date: | October 1, 2024 |
| 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, 2024 |
| Subsection: | Topical Products | Original Policy Date: | January 29, 2021 |
| Subject: | Winlevi | Page: | 4 of 4 |

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|----------------|---|
| 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 |
| September 2024 | Annual review |

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.