

**WINLEVI
(clascoterone)****RATIONALE FOR INCLUSION IN PA PROGRAM****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).

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.