

Winlevi (clascoterone) Prior Authorization Program Summary

POLICY REVIEW CYCLE

Effective Date
02-01-2025

Date of Origin

FDA LABELED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Winlevi® (clascoterone) Cream	Topical treatment of acne vulgaris in patients 12 years of age and older		1

See package insert for FDA prescribing information: <https://dailymed.nlm.nih.gov/dailymed/index.cfm>

CLINICAL RATIONALE

Acne Vulgaris	<p>Acne vulgaris is a common, chronic, inflammatory skin disorder of the pilosebaceous unit. Signs and symptoms include comedones, papules, pustules, or nodules on the face, but may also affect the upper arms, trunk, and back. Acne vulgaris most commonly occurs in adolescents, but it can affect most age groups and can persist into adulthood.(2,3) Topical therapies are the mainstay of acne treatment, and are used alone or in combination with other topical or oral agents. Using a combination of multiple mechanisms of action of topical therapies is recommended as multimodal therapy to optimize efficacy and reduce the risk of antibiotic resistance. Systemic oral antibiotics are typically used to treat moderate to severe acne. (2)</p> <p>Topical retinoids are vitamin A derivatives and are strongly recommended for the treatment of acne by the American Academy of Dermatology (AAD). Topical retinoid agents include tretinoin, adapalene, tazarotene, and trifarotene. Only modest differences in activity, tolerability, and efficacy have been noted between the different retinoids, and comparative effectiveness data does not suggest superiority of one topical retinoid against another.(2)</p> <p>BP is strongly recommended by the AAD for the treatment of acne. BP is a topical antimicrobial agent and is available over-the-counter. BP use is limited by concentration and formulation dependent side effects, including burning, stinging, dryness, erythema, and irritation. (2)</p> <p>Topical antibiotics are strongly recommended by the AAD for the treatment of acne and have both antibacterial and anti-inflammatory effects. Treatment options include erythromycin, clindamycin, minocycline, and dapsone. Topical antibiotic monotherapy is not recommended due to the risk of antibiotic resistance, and they should be used in combination with BP and/or a topical retinoid. There is a lack of evidence to suggest superiority of one topical antibiotic against another.(2)</p> <p>Fixed dose combination products of topical antibiotics, topical retinoids, and/or BP are strongly recommended by the AAD. Fixed dose combination products assist in treatment regimen adherence and may be less expensive than their individual components separately. When using a combination topical retinoid/antibiotic agent, it</p>
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	<p>is recommended to use concomitant BP to prevent antibiotic resistance. Insufficient evidence is available to recommend topical BP, retinoids, antibiotics, or their combinations over one another.(2)</p> <p>Clascoterone (Winlevi) is a topical antiandrogen agent. It is conditionally recommended for the treatment of acne by the AAD due to treatment access and cost, despite a high certainty of benefits over risks. Azelaic acid is a topical comedolytic, antibacterial, and anti-inflammatory agent and is also conditionally recommended for the treatment of acne by the AAD. Azelaic acid may be beneficial for patients with sensitive skin or dyspigmentation due to its lightening effects. Insufficient evidence is available to develop a recommendation on the use of topical sodium sulfacetamide for acne even though it is used in practice.(2)</p>
Safety	Winlevi has no FDA labeled contraindications for use.(1)

REFERENCES

Number	Reference
1	Winlevi prescribing information. Sun Pharmaceutical Industries, Inc. July 2022.
2	Reynolds RV, Yeung H, Cheng CE, et al. Guidelines of care for the management of acne vulgaris. <i>Journal of the American Academy of Dermatology</i> . 2024;90(5):1006.e1-1006.e30. doi:10.1016/j.jaad.2023.12.017
3	Sutaria AH, Masood S, Saleh HM, Schlessinger J. Acne vulgaris. StatPearls - NCBI Bookshelf. Published August 17, 2023. https://www.ncbi.nlm.nih.gov/books/NBK459173/

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Winlevi	clascoterone cream	1 %	M ; N ; O ; Y	N		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Winlevi	clascoterone cream	1 %	Commercial ; HIM ; ResultsRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval		
PA	<p>Winlevi (clascoterone) will be approved when ONE of the following is met:</p> <p>1. The requested agent is eligible for continuation of therapy AND ONE of the following:</p> <table><tr><td>Agents Eligible for Continuation of Therapy</td></tr><tr><td>All target agents are eligible for continuation of therapy</td></tr></table> <p>A. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days OR</p> <p>B. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed OR</p> <p>2. BOTH of the following:</p>	Agents Eligible for Continuation of Therapy	All target agents are eligible for continuation of therapy
Agents Eligible for Continuation of Therapy			
All target agents are eligible for continuation of therapy			

Module	Clinical Criteria for Approval
	<p data-bbox="354 180 1377 642"> A. The patient has a diagnosis of acne vulgaris AND ONE of the following: <ol style="list-style-type: none"> <li data-bbox="472 212 1377 268">1. The patient has tried and had an inadequate response to at least ONE generic topical antibiotic agent used in the treatment of acne OR <li data-bbox="472 268 1377 325">2. The patient has tried and had an inadequate response to at least ONE generic topical retinoid agent used in the treatment of acne OR <li data-bbox="472 325 1377 411">3. The patient has an intolerance or hypersensitivity to a generic topical antibiotic agent OR a generic topical retinoid therapy used in the treatment of acne OR <li data-bbox="472 411 1377 497">4. The patient has an FDA labeled contraindication to ALL generic topical antibiotic agents AND generic topical retinoid agents used in the treatment of acne AND B. If the patient has an FDA labeled indication, then ONE of the following: <ol style="list-style-type: none"> <li data-bbox="472 529 1377 585">1. The patient's age is within FDA labeling for the requested indication for the requested agent OR <li data-bbox="472 585 1377 642">2. There is support for using the requested agent for the patient's age for the requested indication </p> <p data-bbox="233 680 634 711">Length of Approval: 12 months</p>