

# Winlevi Prior Authorization Program Summary

## POLICY REVIEW CYCLE

**Effective Date**  
01-01-2026

**Date of Origin**

## 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 %	IL HMO Performance Annual ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026

## PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval		
PA	<p><b>Target Agent(s)</b> will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> <li>The requested agent is eligible for continuation of therapy AND the following:           <table border="1" data-bbox="235 1669 1226 1743"> <thead> <tr> <th>Agents Eligible for Continuation of Therapy</th> </tr> </thead> <tbody> <tr> <td>All target agents are eligible for continuation of therapy</td> </tr> </tbody> </table> </li> <li>BOTH of the following:           <ol style="list-style-type: none"> <li>ONE of the following:               <ol style="list-style-type: none"> <li>The patient has a diagnosis of acne vulgaris AND ONE of the following:</li> </ol> </li> </ol> </li> </ol>	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="565 180 1354 237">A. Tried and had an inadequate response to ONE generic topical antibiotic used in the treatment of acne <b>OR</b></p> <p data-bbox="565 239 1354 296">B. Tried and had an inadequate response to ONE generic topical retinoid used in the treatment of acne <b>OR</b></p> <p data-bbox="565 298 1414 354">C. An intolerance or hypersensitivity to ONE generic topical antibiotic or generic topical retinoid used in the treatment of acne <b>OR</b></p> <p data-bbox="565 357 1395 413">D. An FDA labeled contraindication to ALL generic topical antibiotics AND generic topical retinoids used in the treatment of acne <b>OR</b></p> <p data-bbox="472 415 1300 472">2. The patient has another FDA labeled indication for the requested agent and route of administration <b>AND</b></p> <p data-bbox="355 474 1279 501">B. If the patient has an FDA labeled indication, then ONE of the following:</p> <p data-bbox="472 504 1377 560">A. The patient's age is within FDA labeling for the requested indication for the requested agent <b>OR</b></p> <p data-bbox="472 562 1377 619">B. There is support for using the requested agent for the patient's age for the requested indication</p> <p data-bbox="232 653 498 680"><b>Length of Approval:</b></p> <p data-bbox="232 720 483 747">BCBSOK: 36 months</p> <p data-bbox="232 787 568 814">ALL other plans: 12 months</p> <p data-bbox="232 917 1268 945"><b>The requested agent will also be approved when ONE of the following is met:</b></p> <p data-bbox="280 984 1401 1012">1. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following:</p> <p data-bbox="355 1014 1377 1071">A. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></p> <p data-bbox="355 1073 992 1100">B. The requested indication is a rare disease <b>AND</b></p> <p data-bbox="355 1102 678 1129">C. ONE of the following:</p> <p data-bbox="472 1131 1377 1188">1. The patient has another FDA labeled indication for the requested agent and route of administration <b>OR</b></p> <p data-bbox="472 1190 1401 1247">2. The patient has another indication that is supported in compendia for the requested agent and route of administration <b>OR</b></p> <p data-bbox="280 1249 574 1276">2. ALL of the following:</p> <p data-bbox="355 1278 829 1306">A. The member resides in Ohio <b>AND</b></p> <p data-bbox="355 1308 1010 1335">B. The plan is Fully Insured or HIM Shop (SG) <b>AND</b></p> <p data-bbox="355 1337 1377 1394">C. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></p> <p data-bbox="355 1396 678 1423">D. ONE of the following:</p> <p data-bbox="472 1425 1377 1482">1. The patient has another FDA labeled indication for the requested agent and route of administration <b>OR</b></p> <p data-bbox="472 1484 1401 1541">2. The patient has another indication that is supported in compendia for the requested agent and route of administration <b>OR</b></p> <p data-bbox="472 1543 1401 1738">3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required]</p> <p data-bbox="232 1778 1395 1835"><b>Non-oncology compendia allowed:</b> DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p data-bbox="232 1875 1377 1955"><b>Oncology compendia allowed:</b> NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p>

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	<p data-bbox="232 180 500 212"><b>Length of Approval:</b></p> <p data-bbox="232 247 483 279">BCBSOK: 36 months</p> <p data-bbox="232 315 570 346">ALL other plans: 12 months</p>