



# Zelsuvmi Prior Authorization with Quantity Limit Program Summary

## POLICY REVIEW CYCLE

**Effective Date**  
12-15-2025

**Date of Origin**  
05-16-2024

## POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Zelsuvmi	berdazimer sodium gel	10.3 %	M ; N ; O ; Y	N		

## POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Zelsuvmi	berdazimer sodium gel	10.3 %	2	Kits	84	DAYS			

## CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Zelsuvmi	berdazimer sodium gel	10.3 %	Balanced ; Balanced Biosimilar ; 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 HMO Performance Quarterly ; 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 ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

## CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Zelsuvmi	berdazimer sodium gel	10.3 %	Balanced ; Balanced Biosimilar ; 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 HMO Performance Quarterly ; 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 ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

## PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	<p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>1. ONE of the following: <ol style="list-style-type: none"> <li>A. The patient has a diagnosis of molluscum contagiosum (MC) <b>OR</b></li> <li>B. The patient has another FDA labeled indication for the requested agent <b>AND</b></li> </ol> </li> <li>2. If the patient has an FDA labeled indication, then ONE of the following: <ol style="list-style-type: none"> <li>A. The patient’s age is within FDA labeling for the requested indication for the requested agent <b>OR</b></li> <li>B. There is support for using the requested agent for the patient’s age for the requested indication <b>AND</b></li> </ol> </li> <li>3. ONE of the following: <ol style="list-style-type: none"> <li>A. BOTH of the following: <ol style="list-style-type: none"> <li>1. ONE of the following: <ol style="list-style-type: none"> <li>A. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer <b>OR</b></li> <li>B. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat an associated condition related to stage four advanced, metastatic cancer [chart notes required] <b>AND</b></li> </ol> </li> <li>2. The use of the requested agent is consistent with best practices for the treatment of stage four advanced, metastatic cancer, or an associated condition; supported by peer-reviewed, evidence-based literature; and approved by the United States Food and Drug Administration <b>OR</b></li> </ol> </li> <li>B. The patient has tried and had an inadequate response to ONE conventional therapy (e.g., cantharidin, cryotherapy, curettage, podofilox) <b>OR</b></li> <li>C. The patient has an intolerance or hypersensitivity to ONE conventional therapy <b>OR</b></li> <li>D. The patient has an FDA labeled contraindication to ALL conventional therapy <b>OR</b></li> <li>E. There is support that conventional therapy is NOT recommended for the patient <b>AND</b></li> </ol> </li> <li>4. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., dermatologist), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis <b>AND</b></li> <li>5. The patient will NOT be using the requested agent in combination with another conventional therapy (e.g., cantharidin, cryotherapy, curettage, podofilox) for the requested indication <b>AND</b></li> </ol>

Module	Clinical Criteria for Approval
	<p>6. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p><b>Length of Approval:</b></p> <p>BCBSIL and BCBSMT: 6 months</p> <p>ALL other plans: 12 weeks</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p><b>The requested agent will also be approved when ONE of the following is met:</b></p> <ol style="list-style-type: none"> <li>1. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following: <ol style="list-style-type: none"> <li>A. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></li> <li>B. The requested indication is a rare disease <b>AND</b></li> <li>C. ONE of the following: <ol style="list-style-type: none"> <li>1. The patient has another FDA labeled indication for the requested agent and route of administration <b>OR</b></li> <li>2. The patient has another indication that is supported in compendia for the requested agent and route of administration <b>OR</b></li> </ol> </li> </ol> </li> <li>2. ALL of the following: <ol style="list-style-type: none"> <li>A. The member resides in Ohio <b>AND</b></li> <li>B. The plan is Fully Insured or HIM Shop (SG) <b>AND</b></li> <li>C. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></li> <li>D. ONE of the following: <ol style="list-style-type: none"> <li>1. The patient has another FDA labeled indication for the requested agent and route of administration <b>OR</b></li> <li>2. The patient has another indication that is supported in compendia for the requested agent and route of administration <b>OR</b></li> <li>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]</li> </ol> </li> </ol> </li> </ol> <p><b>Non-oncology compendia allowed:</b> DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p><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> <p><b>Length of Approval:</b> 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

### QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p><b>Quantity Limit for the Target Agent(s)</b> will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the program quantity limit <b>OR</b></li> <li>2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following:</li> </ol>

Module	Clinical Criteria for Approval
	<p data-bbox="375 184 1417 527"> A. BOTH of the following: <ol style="list-style-type: none"> <li data-bbox="472 212 1417 268">1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication <b>AND</b></li> <li data-bbox="472 268 1417 325">2. There is support for therapy with a higher dose for the requested indication <b>OR</b></li> </ol> B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication <b>OR</b> C. BOTH of the following: <ol style="list-style-type: none"> <li data-bbox="472 415 1417 472">1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication <b>AND</b></li> <li data-bbox="472 472 1417 527">2. There is support for therapy with a higher dose for the requested indication</li> </ol> </p> <p data-bbox="232 569 505 600"><b>Length of Approval:</b></p> <p data-bbox="232 632 431 657">BCBSIL: 12 months</p> <p data-bbox="232 695 500 720">ALL other plans: 12 weeks</p>