



# Opzelura Prior Authorization with Quantity Limit Program Summary

## POLICY REVIEW CYCLE

**Effective Date**  
02-25-2026

**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
Opzelura	ruxolitinib phosphate cream	1.5 %	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
Opzelura	Ruxolitinib Phosphate Cream	1.5 %	60	Grams	30	DAYS			

## CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Opzelura	ruxolitinib phosphate cream	1.5 %	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; 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 ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; 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
Opzelura	Ruxolitinib Phosphate Cream	1.5 %	Balanced ; Balanced Biosimilar ; Basic ; Basic

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Annual ; Enhanced ; Enhanced Annual ; 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 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; 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>Initial Evaluation</b></p> <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 mild to moderate atopic dermatitis (AD) AND ALL of the following: <ol style="list-style-type: none"> <li>1. The patient is NOT immunocompromised <b>AND</b></li> <li>2. The patient has ONE of the following: <ol style="list-style-type: none"> <li>A. Tried and had an inadequate response to ONE at least low-potency topical corticosteroid used in the treatment of AD after at least a 4-week duration of therapy <b>OR</b></li> <li>B. An intolerance or hypersensitivity to ONE at least low-potency topical corticosteroid used in the treatment of AD <b>OR</b></li> <li>C. An FDA labeled contraindication to ALL topical corticosteroids used in the treatment of AD <b>AND</b></li> </ol> </li> <li>3. The patient has ONE of the following: <ol style="list-style-type: none"> <li>A. Tried and had an inadequate response to ONE topical calcineurin inhibitor used in the treatment of AD after at least a 6-week duration of therapy <b>OR</b></li> <li>B. An intolerance or hypersensitivity to ONE topical calcineurin inhibitor used in the treatment of AD <b>OR</b></li> <li>C. An FDA labeled contraindication to ALL topical calcineurin inhibitors used in the treatment of AD <b>AND</b></li> </ol> </li> <li>4. BOTH of the following: <ol style="list-style-type: none"> <li>A. The patient is currently treated with topical emollients and practicing good skin care <b>AND</b></li> <li>B. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent <b>OR</b></li> </ol> </li> </ol> </li> <li>B. The patient has a diagnosis of nonsegmental vitiligo (NSV) AND ALL of the following: <ol style="list-style-type: none"> <li>1. The patient's affected body surface area (BSA) is less than or equal to 10% <b>AND</b></li> <li>2. 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> </ol> </li> </ol> </li> </ol> </li> </ol> </li> </ol> </li></ol>

Module	Clinical Criteria for Approval
	<p style="text-align: center;">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></p> <p>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></p> <p>B. The patient has ONE of the following:</p> <ol style="list-style-type: none"> <li>1. Tried and had an inadequate response to ONE at least medium-potency topical corticosteroid used in the treatment of NSV after at least a 12-week duration of therapy <b>OR</b></li> <li>2. Tried and had an inadequate response to ONE topical calcineurin inhibitor used in the treatment of NSV after at least a 12-week duration of therapy <b>OR</b></li> <li>3. An intolerance or hypersensitivity to ONE at least medium-potency topical corticosteroid or topical calcineurin inhibitor used in the treatment of NSV <b>OR</b></li> <li>4. An FDA labeled contraindication to ALL medium-, high-, and super-potency topical corticosteroids AND ALL topical calcineurin inhibitors used in the treatment of NSV <b>OR</b></li> </ol> <p>C. The patient has another FDA labeled indication for the requested agent and route of administration <b>AND</b></p> <ol style="list-style-type: none"> <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. 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>4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): <ol style="list-style-type: none"> <li>A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) <b>OR</b></li> <li>B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: <ol style="list-style-type: none"> <li>1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent <b>AND</b></li> <li>2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, orguidelines required) <b>AND</b></li> </ol> </li> </ol> </li> <li>5. The patient does NOT have any FDA labeled contraindications to the requested agent</li> </ol> <p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months</p> <p>BCBSIL, BCBSMT, and BCBSTX: 12 months</p> <p>ALL other plans: 3 months for atopic dermatitis; 6 months for nonsegmental vitiligo; 12 months for all other indications</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

Module	Clinical Criteria for Approval
	<p><b>The requested agent will also be approved when the following are met:</b></p> <ol style="list-style-type: none"> <li>1. The member resides in Ohio <b>AND</b></li> <li>2. The plan is Fully Insured or HIM Shop (SG) <b>AND</b> BOTH 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. 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></p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p><b>Renewal Evaluation</b></p> <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. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (Note: patients not previously approved for the requested agent will require initial evaluation review) <b>AND</b></li> <li>2. The patient has had clinical benefit with the requested agent <b>AND</b></li> <li>3. If the patient has a diagnosis of mild to moderate atopic dermatitis, then the patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent <b>AND</b></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. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): <ol style="list-style-type: none"> <li>A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) <b>OR</b></li> <li>B. The patient will be using the requested agent in combination with another immunomodulatory agent <b>AND</b> BOTH of the following: <ol style="list-style-type: none"> <li>1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent <b>AND</b></li> <li>2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) <b>AND</b></li> </ol> </li> </ol> </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>BCBSOK: 36 months</p> <p>ALL other plans: 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: <ol style="list-style-type: none"> <li>A. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. There is support for therapy with a higher dose for the requested indication <b>OR</b></li> </ol> </li> <li>B. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit <b>OR</b></li> </ol> </li> <li>C. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. There is support for therapy with a higher dose for the requested indication</li> </ol> </li> </ol> </li> </ol> <p><b>Length of Approval:</b></p> <p>BCBSIL: 12 months</p> <p>INITIAL: ALL other plans: 3 months for atopic dermatitis; 6 months for nonsegmental vitiligo; 12 months all other indications</p> <p>RENEWAL: 12 months</p>

## CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
<p><b>Agents NOT to be used Concomitantly</b></p> <p>Abrilada (adalimumab-afzb)</p> <p>Actemra (tocilizumab)</p> <p>Adalimumab</p> <p>Adbry (tralokinumab-ldrm)</p> <p>Amjevita (adalimumab-atto)</p> <p>Arcalyst (rilonacept)</p> <p>Avsola (infliximab-axxq)</p> <p>Avtozma (tocilizumab-anoh)</p> <p>Benlysta (belimumab)</p>

**Contraindicated as Concomitant Therapy**

Bimzelx (bimekizumab-bkzx)  
Cibinqo (abrocitinib)  
Cimzia (certolizumab)  
Cinqair (reslizumab)  
Cosentyx (secukinumab)  
Cyltezo (adalimumab-adbm)  
Dupixent (dupilumab)  
Ebglyss (lebrikizumab-lbkz)  
Enbrel (etanercept)  
Entyvio (vedolizumab)  
Fasenra (benralizumab)  
Hadlima (adalimumab-bwwd)  
Hulio (adalimumab-fkjp)  
Humira (adalimumab)  
Hyrimoz (adalimumab-adaz)  
Idacio (adalimumab-aacf)  
Ilaris (canakinumab)  
Ilumya (tildrakizumab-asmn)  
Imuldosa (ustekinumab-srlf)  
Inflectra (infliximab-dyyb)  
Infliximab  
Kevzara (sarilumab)  
Kineret (anakinra)  
Leqselvi (deuruxolitinib)  
Litfulo (ritlecitinib)  
Nemludio (nemolizumab-ilto)  
Nucala (mepolizumab)  
Olumiant (baricitinib)  
Omyclo (omalizumab-igec)  
Omvoh (mirikizumab-mrkz)  
Opzelura (ruxolitinib)  
Orencia (abatacept)  
Otezla (apremilast)  
Otulfi (ustekinumab-aaaz)  
Pyzchiva (ustekinumab-ttwe)  
Remicade (infliximab)  
Renflexis (infliximab-abda)  
Riabni (rituximab-arrx)  
Rinvoq (upadacitinib)  
Rituxan (rituximab)  
Rituxan Hycela (rituximab/hyaluronidase human)  
Ruxience (rituximab-pvvr)  
Saphnelo (anifrolumab-fnia)  
Selarsdi (ustekinumab-aekn)  
Siliq (brodalumab)  
Simlandi (adalimumab-ryvk)  
Simponi (golimumab)  
Simponi ARIA (golimumab)  
Skyrizi (risankizumab-rzaa)  
Sotyktu (deucravacitinib)  
Spevigo (spesolimab-sbzo) subcutaneous injection  
Starjemza (ustekinumab-hmny)  
Stelara (ustekinumab)  
Steqeyma (ustekinumab-stba)  
Taltz (ixekizumab)  
Tezspire (tezepelumab-ekko)  
Tofidence (tocilizumab-bavi)  
Tremfya (guselkumab)  
Truxima (rituximab-abbs)  
Tyenne (tocilizumab-aazg)  
Tysabri (natalizumab)  
Ustekinumab

**Contraindicated as Concomitant Therapy**

Velsipity (etrasimod)  
Wezlana (ustekinumab-auub)  
Xeljanz (tofacitinib)  
Xeljanz XR (tofacitinib extended release)  
Xolair (omalizumab)  
Yesintek (ustekinumab-kfce)  
Yuflyma (adalimumab-aaty)  
Yusimry (adalimumab-aqvh)  
Zeposia (ozanimod)  
Zymfentra (infliximab-dyyb)