



# Topical Doxepin Prior Authorization with Quantity Limit Program Summary

## POLICY REVIEW CYCLE

**Effective Date**  
02-01-2026

**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
Prudoxin ; Zonalon	Doxepin HCl Cream 5%	5 %	M ; N ; O ; Y	O ; Y		

## 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
Prudoxin ; Zonalon	Doxepin HCl Cream 5%	5 %	45	Grams	30	DAYS			

## CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Prudoxin ; Zonalon	Doxepin HCl Cream 5%	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 ; 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
Prudoxin ; Zonalon	Doxepin HCl Cream 5%	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 ; 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
	<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. BOTH of the following: <ol style="list-style-type: none"> <li>1. The patient has ONE of the following: <ol style="list-style-type: none"> <li>A. A diagnosis of moderate pruritus associated with atopic dermatitis (AD) AND ALL of the following: <ol style="list-style-type: none"> <li>1. The patient has ONE of the following: <ol style="list-style-type: none"> <li>A. Tried and had an inadequate response to ONE 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 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>2. 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>3. 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. A diagnosis of moderate pruritus associated with lichen simplex chronicus AND ONE of the following: <ol style="list-style-type: none"> <li>1. Tried and had an inadequate response to ONE topical corticosteroid <b>OR</b></li> </ol> </li> </ol> </li> </ol> </li> </ol> </li></ol>

Module	Clinical Criteria for Approval						
	<p>2. An intolerance or hypersensitivity to ONE topical corticosteroid <b>OR</b></p> <p>3. An FDA labeled contraindication to ALL topical corticosteroids <b>AND</b></p> <p>2. The patient has NOT already received 8 days of therapy with a topical doxepin agent for the current course of therapy <b>OR</b></p> <p>B. The patient has another FDA labeled indication for the requested agent and route of administration <b>OR</b></p> <p>C. The patient has an indication that is supported in compendia for the requested agent and route of administration <b>AND</b></p> <p>2. If the patient has an FDA labeled indication, then ONE of the following:</p> <p>A. The patient's age is within FDA labeling for the requested indication for the requested agent <b>OR</b></p> <p>B. There is support for using the requested agent for the patient's age for the requested indication <b>AND</b></p> <p>3. If the request is for one of the following brand agents with an available generic equivalent, then ONE of the following:</p> <table border="1" data-bbox="237 772 1227 884"> <thead> <tr> <th data-bbox="237 772 732 814">Brand</th> <th data-bbox="732 772 1227 814">Generic Equivalent</th> </tr> </thead> <tbody> <tr> <td data-bbox="237 814 732 846">Prudoxin cream</td> <td data-bbox="732 814 1227 846">doxepin hydrochloride cream 5%</td> </tr> <tr> <td data-bbox="237 846 732 884">Zonalon cream</td> <td data-bbox="732 846 1227 884"></td> </tr> </tbody> </table> <p>3.</p> <p>A. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member <b>OR</b></p> <p>B. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes are required] <b>OR</b></p> <p>C. The patient has tried and had an inadequate response to the generic [chart notes are required] <b>OR</b></p> <p>D. The generic was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] <b>OR</b></p> <p>E. The patient has an intolerance or hypersensitivity to the generic that is not expected to occur with the brand agent [chart notes are required] <b>OR</b></p> <p>F. The patient has an FDA labeled contraindication to the generic that is not expected to occur with the brand agent [chart notes are required] <b>OR</b></p> <p>G. The generic is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; <b>OR</b> cause a significant barrier to the patient's adherence of care; <b>OR</b> worsen a comorbid condition; <b>OR</b> decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; <b>OR</b> cause an adverse reaction or cause physical or mental harm [chart notes are required] <b>OR</b></p> <p>H. The generic is not in the best interest of the patient based on medical necessity [chart notes are required] <b>OR</b></p> <p>I. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as the generic and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] <b>OR</b></p> <p>J. There is support for the use of the requested brand agent over the generic <b>AND</b></p> <p>4. The patient will NOT be using the requested agent in combination with another topical doxepin agent <b>AND</b></p> <p>5. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p><b>Compendia Allowed: AHFS or DrugDex 1, 2a or 2b level of evidence</b></p>	Brand	Generic Equivalent	Prudoxin cream	doxepin hydrochloride cream 5%	Zonalon cream	
Brand	Generic Equivalent						
Prudoxin cream	doxepin hydrochloride cream 5%						
Zonalon cream							

Module	Clinical Criteria for Approval
	<p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months  BCBSIL and BCBSMT: 12 months  BCBSNM: pruritus associated with atopic dermatitis or lichen simplex chronicus - 3 months; or all other requests - 12 months  All other plans: pruritus associated with atopic dermatitis or lichen simplex chronicus - 1 month; or all other requests - 12 months</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></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. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication <b>OR</b></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><b>BCBSIL:</b> 12 months  <b>All other plans:</b> pruritus associated with atopic dermatitis or lichen simplex chronicus - 1 month; or all other requests - 12 months</p>