

# Topical Lidocaine Prior Authorization with Quantity Limit Program Summary

## POLICY REVIEW CYCLE

**Effective Date**  
04-01-2026

**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
Premium lidocaine	Lidocaine Oint 5%	5 %	M ; N ; O ; Y	N ; Y		
Ztlido	Lidocaine Patch 1.8% (36 MG)	1.8 %	M ; N ; O ; Y	N		
Lidoderm	Lidocaine Patch 5%	5 %	M ; N ; O ; Y	O ; Y		
Pliaglis	Lidocaine-Tetracaine Cream 7-7%	7-7 %	M ; N ; O ; Y	M ; 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
	Lidocaine HCl Soln 4%	4 %	150	mLs	30	DAYS			
	Lidocaine HCl Urethral/Mucosal Gel Prefilled Syringe 2%	2 %	150	mLs	30	DAYS			
	Lidocaine-Prilocaine Cream 2.5-2.5%	2.5-2.5 %	60	Grams	30	DAYS			
Lidocaine hydrochloride j	Lidocaine HCl Urethral/Mucosal Gel 2%	2 %	150	mLs	30	DAYS			
Lidoderm	Lidocaine Patch 5%	5 %	90	Patches	30	DAYS			
Pliaglis	Lidocaine-Tetracaine Cream 7-7%	7-7 %	120	Grams	30	DAYS			
Premium lidocaine	Lidocaine Oint 5%	5 %	100	Grams	30	DAYS			
Ztlido	Lidocaine Patch 1.8% (36 MG)	1.8 %	90	Systems	30	DAYS			

## CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Lidoderm	Lidocaine Patch 5%	5 %	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			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
Pliaglis	Lidocaine-Tetracaine Cream 7-7%	7-7 %	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 Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Premium lidocaine	Lidocaine Oint 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 Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Ztlido	Lidocaine Patch 1.8% (36 MG)	1.8 %	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			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

### CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
	Lidocaine HCl Soln 4%	4 %	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 Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
	Lidocaine HCl Urethral/Mucosal Gel Prefilled Syringe 2%	2 %	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 Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
	Lidocaine-Prilocaine Cream 2.5-2.5%	2.5-2.5 %	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			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
Lidocaine hydrochloride j	Lidocaine HCl Urethral/Mucosal Gel 2%	2 %	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 Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Lidoderm	Lidocaine Patch 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 Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Pliaglis	Lidocaine-Tetracaine Cream 7-7%	7-7 %	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

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			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
Premium lidocaine	Lidocaine Oint 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 Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Ztlido	Lidocaine Patch 1.8% (36 MG)	1.8 %	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 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
lidocaine topical ointment 5%	<p><b>lidocaine topical ointment 5%</b> will be approved when BOTH of the following are met:</p> <ol style="list-style-type: none"> <li>The requested agent will be used for ONE of the following indications: <ul style="list-style-type: none"> <li>A. Anesthesia of accessible mucous membranes of the oropharynx <b>OR</b></li> <li>B. Anesthetic lubricant for intubation <b>OR</b></li> </ul> </li> </ol>

Module	Clinical Criteria for Approval
	<p>C. BOTH of the following:</p> <ol style="list-style-type: none"> <li>1. The patient has ONE of the following:           <ol style="list-style-type: none"> <li>A. Pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites <b>OR</b></li> <li>B. Another FDA labeled indication for the requested agent and route of administration <b>OR</b></li> <li>C. Another indication that is supported in compendia for the requested agent and route of administration <b>AND</b></li> </ol> </li> <li>2. ONE of the following:           <ol style="list-style-type: none"> <li>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></li> <li>B. 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>C. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] <b>OR</b></li> <li>D. The patient has tried and had an inadequate response to over-the-counter topical lidocaine [chart notes required] <b>OR</b></li> <li>E. Over-the-counter topical lidocaine was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] <b>OR</b></li> <li>F. The patient has an intolerance or hypersensitivity to over-the-counter topical lidocaine that is not expected to occur with the requested agent [chart notes required] <b>OR</b></li> <li>G. The patient has an FDA labeled contraindication to ALL over-the-counter topical lidocaine that is not expected to occur with the requested agent [chart notes required] <b>OR</b></li> <li>H. Over-the-counter topical lidocaine 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 required] <b>OR</b></li> <li>I. Over-the-counter topical lidocaine is not in the best interest of the patient based on medical necessity [chart notes required] <b>OR</b></li> <li>J. The patient has tried another drug in the same pharmacologic class or with the same mechanism of action as over-the-counter topical lidocaine and that drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] <b>OR</b></li> <li>K. The prescriber has provided information that indicates over-the-counter topical lidocaine is NOT clinically appropriate <b>AND</b></li> </ol> </li> </ol> <p>2. The patient does NOT have any FDA labeled contraindications to the requested agent</p>

Module	Clinical Criteria for Approval
	<p><b>Compendia Allowed:</b> AHFS, DrugDex 1, 2a, or 2b level of evidence, or NCCN 1, 2a, or 2b recommended use</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>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>

Module	Clinical Criteria for Approval
Lidoderm (lidocaine patch 5%) and ZTlido (lidocaine topical system 1.8%)	<p><b>Lidoderm (lidocaine patch 5%) and ZTlido (lidocaine topical system 1.8%)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>1. The requested agent will be used for ONE of the following indications: <ol style="list-style-type: none"> <li>A. Pain associated with post-herpetic neuralgia (PHN) <b>OR</b></li> <li>B. Neuropathic pain associated with cancer or cancer treatment <b>OR</b></li> <li>C. Another FDA labeled indication for the requested agent and route of administration <b>OR</b></li> <li>D. Another indication that is supported in compendia for the requested agent and route of administration <b>AND</b></li> </ol> </li> <li>2. ONE of the following: <ol style="list-style-type: none"> <li>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></li> <li>B. 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>C. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] <b>OR</b></li> <li>D. The patient has tried and had an inadequate response to over-the-counter topical lidocaine [chart notes required] <b>OR</b></li> <li>E. Over-the-counter topical lidocaine was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] <b>OR</b></li> <li>F. The patient has an intolerance or hypersensitivity to over-the-counter topical lidocaine that is not expected to occur with the requested agent [chart notes required] <b>OR</b></li> <li>G. The patient has an FDA labeled contraindication to ALL over-the-counter topical lidocaine that is not expected to occur with the requested agent [chart notes required] <b>OR</b></li> <li>H. Over-the-counter topical lidocaine 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 required] <b>OR</b></li> <li>I. Over-the-counter topical lidocaine is not in the best interest of the patient based on medical necessity [chart notes required] <b>OR</b></li> <li>J. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as over-the-counter topical lidocaine and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] <b>OR</b></li> <li>K. The prescriber has provided information that indicates over-the-counter topical lidocaine is NOT clinically appropriate <b>AND</b></li> </ol> </li> <li>3. The patient does NOT have any FDA labeled contraindications to the requested agent</li> </ol> <p><b>Compendia Allowed:</b> AHFS, DrugDex 1, 2a, or 2b level of evidence, or NCCN 1, 2a, or 2b recommended use</p> <p><b>Length of Approval:</b></p>

Module	Clinical Criteria for Approval
	<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>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>
Pliaglis (lidocaine 7%/tetracaine cream 7%)	<p><b>Pliaglis (lidocaine 7%/tetracaine cream 7%)</b> will be approved when BOTH of the following are met:</p> <ol style="list-style-type: none"> <li>1. The requested agent will be used for ONE of the following indications: <ol style="list-style-type: none"> <li>A. Analgesia for superficial dermatological procedures such as dermal filler injection, pulsed dye laser therapy, facial laser resurfacing, and laser-assisted tattoo removal <b>OR</b></li> <li>B. BOTH of the following:</li> </ol> </li> </ol>

Module	Clinical Criteria for Approval
	<ol style="list-style-type: none"> <li>1. The patient has ONE of the following:               <ol style="list-style-type: none"> <li>A. Another FDA labeled indication for the requested agent and route of administration <b>OR</b></li> <li>B. Another indication that is supported in compendia for the requested agent and route of administration <b>AND</b></li> </ol> </li> <li>2. ONE of the following:               <ol style="list-style-type: none"> <li>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></li> <li>B. 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>C. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] <b>OR</b></li> <li>D. The patient has tried and had an inadequate response to over-the-counter topical lidocaine [chart notes required] <b>OR</b></li> <li>E. Over-the-counter topical lidocaine was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] <b>OR</b></li> <li>F. The patient has an intolerance or hypersensitivity to over-the-counter topical lidocaine that is not expected to occur with the requested agent [chart notes required] <b>OR</b></li> <li>G. The patient has an FDA labeled contraindication to ALL over-the-counter topical lidocaine that is not expected to occur with the requested agent [chart notes required] <b>OR</b></li> <li>H. Over-the-counter topical lidocaine 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 required] <b>OR</b></li> <li>I. Over-the-counter topical lidocaine is not in the best interest of the patient based on medical necessity [chart notes required] <b>OR</b></li> <li>J. The patient has tried another drug in the same pharmacologic class or with the same mechanism of action as over-the-counter topical lidocaine and that drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] <b>OR</b></li> <li>K. The prescriber has provided information that indicates over-the-counter topical lidocaine is NOT clinically appropriate <b>AND</b></li> </ol> </li> <li>2. The patient does NOT have any FDA labeled contraindications to the requested agent</li> </ol> <p><b>Compendia Allowed:</b> AHFS, DrugDex 1, 2a, or 2b level of evidence, or NCCN 1, 2a, or 2b recommended use</p>

Module	Clinical Criteria for Approval
	<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>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> </ol>

Module	Clinical Criteria for Approval
	<p>2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following:</p> <ul style="list-style-type: none"> <li>A. BOTH of the following: <ul 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> </ul> </li> <li>B. BOTH of the following: <ul 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> </ul> </li> <li>C. BOTH of the following: <ul 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> </ul> </li> </ul> <p><b>Length of Approval:</b> 12 months</p>