

# Oxybate Prior Authorization with Quantity Limit Program Summary

## POLICY REVIEW CYCLE

**Effective Date**

03-15-2026

**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
Xywav	calcium, mag, potassium, & sod oxybates oral soln	500 MG/ML	M ; N ; O ; Y	N		
Lumryz ; Lumryz starter pack ; Sodium oxybate ; Xyrem	sodium oxybate oral solution ; sodium oxybate pack for er susp ; sodium oxybate pack for oral er susp	4.5 & 6 & 7.5 GM ; 4.5 GM ; 500 MG/ML ; 6 GM ; 7.5 GM ; 9 GM	M ; N ; O ; Y	M ; N ; 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
Lumryz	sodium oxybate pack for oral er susp	4.5 GM ; 6 GM ; 7.5 GM ; 9 GM	30	Packets	30	DAYS			
Lumryz starter pack	sodium oxybate pack for er susp	4.5 & 6 & 7.5 GM	28	Packets	180	DAYS			
Sodium oxybate ; Xyrem	sodium oxybate oral solution	500 MG/ML	540	mLs	30	DAYS			
Xywav	calcium, mag, potassium, & sod oxybates oral soln	500 MG/ML	540	mLs	30	DAYS			

## CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Lumryz ; Lumryz starter pack ; Sodium oxybate ; Xyrem	sodium oxybate oral solution ; sodium oxybate pack for er susp ; sodium oxybate pack for oral er susp	4.5 & 6 & 7.5 GM ; 4.5 GM ; 500 MG/ML ; 6 GM ; 7.5 GM ; 9 GM	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

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Xywav	calcium, mag, potassium, & sod oxybates oral soln	500 MG/ML	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
Lumryz	sodium oxybate pack for oral er susp	4.5 GM ; 6 GM ; 7.5 GM ; 9 GM	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
Lumryz starter pack	sodium oxybate pack for er susp	4.5 & 6 & 7.5 GM	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 ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Sodium oxybate ; Xyrem	sodium oxybate oral solution	500 MG/ML	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
Xywav	calcium, mag, potassium, & sod oxybates oral soln	500 MG/ML	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
	<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 ONE of the following: <ol style="list-style-type: none"> <li>A. A diagnosis of narcolepsy with cataplexy or narcolepsy with excessive daytime sleepiness AND ONE of the following: <ol style="list-style-type: none"> <li>1. 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>2. BOTH of the following: <ol style="list-style-type: none"> <li>A. ONE of the following:</li> </ol> </li> </ol> </li> </ol> </li> </ol>

Module	Clinical Criteria for Approval
	<ol style="list-style-type: none"> <li>1. 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>2. 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 <b>AND</b> <ol style="list-style-type: none"> <li>B. 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>3. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent <b>OR</b></li> <li>4. The patient has tried and had an inadequate response to ONE prerequisite agent (i.e., modafinil or armodafinil) <b>OR</b></li> <li>5. ONE prerequisite agent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event <b>OR</b></li> <li>6. The patient has an intolerance or hypersensitivity to ONE prerequisite agent <b>OR</b></li> <li>7. The patient has an FDA labeled contraindication to ALL prerequisite agent(s) <b>OR</b></li> <li>8. ONE prerequisite agent 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 <b>OR</b></li> <li>9. ONE prerequisite agent is not in the best interest of the patient based on medical necessity <b>OR</b></li> <li>10. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE prerequisite agent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event <b>OR</b> <ol style="list-style-type: none"> <li>B. A diagnosis of idiopathic hypersomnia AND ALL of the following:           <ol style="list-style-type: none"> <li>1. The requested agent is Xywav <b>AND</b></li> <li>2. Has completed a sleep study <b>AND</b></li> <li>3. All other causes of hypersomnia have been ruled out <b>AND</b></li> <li>4. ONE of the following:               <ol style="list-style-type: none"> <li>A. Tried and had an inadequate response to modafinil <b>OR</b></li> <li>B. An intolerance or hypersensitivity to modafinil <b>OR</b></li> <li>C. An FDA labeled contraindication to modafinil <b>OR</b></li> </ol> </li> </ol> </li> <li>C. Another FDA labeled indication for the requested agent and route of administration <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. If the request is for brand Xyrem, then then 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</li> </ol> </li> </ol> </li> </ol> </li> </ol>

Module	Clinical Criteria for Approval
	<p style="text-align: center;">an associated condition related to stage four advanced metastatic cancer <b>AND</b></p> <ol style="list-style-type: none"> <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> <li>C. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent <b>OR</b></li> <li>D. The patient has tried and had an inadequate response to authorized generic Sodium Oxybate <b>OR</b></li> <li>E. Authorized generic Sodium Oxybate was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event <b>OR</b></li> <li>F. The patient has an intolerance or hypersensitivity to authorized generic Sodium Oxybate that is NOT expected to occur with the requested agent <b>OR</b></li> <li>G. The patient has an FDA labeled contraindication to authorized generic Sodium Oxybate that is not expected to occur with the requested agent <b>OR</b></li> <li>H. Authorized generic Sodium Oxybate 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 <b>OR</b></li> <li>I. Authorized generic Sodium Oxybate is not in the best interest of the patient based on medical necessity <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 authorized generic Sodium Oxybate and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event <b>OR</b></li> <li>K. There is support for the use of the requested brand agent over authorized generic Sodium Oxybate <b>AND</b></li> <li>4. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., sleep specialist, neurologist, psychiatrist), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis <b>AND</b></li> <li>5. The patient does NOT have any FDA labeled contraindications to the requested agent</li> </ol> <p><b>Length of Approval:</b> 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 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>

Module	Clinical Criteria for Approval
	<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: <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</li> </ol> </li> </ol> </li> </ol> <p><b>Length of Approval:</b> 12 months</p>