

Primary Biliary Cholangitis Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
11-01-2025

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
Iqirvo	elafibrnor tab	80 MG	M ; N ; O ; Y	N		
Ocaliva	Obeticholic Acid Tab 10 MG	10 MG	M ; N ; O ; Y	N		
Ocaliva	Obeticholic Acid Tab 5 MG	5 MG	M ; N ; O ; Y	N		
Livdelzi	seladelpar lysine cap	10 MG	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
Iqirvo	elafibrnor tab	80 MG	30	Tablets	30	DAYS			
Livdelzi	seladelpar lysine cap	10 MG	30	Tablets	30	DAYS			
Ocaliva	Obeticholic Acid Tab 10 MG	10 MG	30	Tablets	30	DAYS			
Ocaliva	Obeticholic Acid Tab 5 MG	5 MG	30	Tablets	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Iqirvo	elafibrnor tab	80 MG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; IL HIM Annual 2025 ; Jade ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			2025 ; Topaz ; Whole Foods
Livdelzi	seladelpar lysine cap	10 MG	IL HMO Performance Annual ; 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 non-HMO Performance Full ; Jade ; MT 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
Ocaliva	Obeticholic Acid Tab 10 MG	10 MG	IL HMO Performance Annual ; 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 non-HMO Performance Full ; Jade ; MT 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
Ocaliva	Obeticholic Acid Tab 5 MG	5 MG	IL HMO Performance Annual ; 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 non-HMO Performance Full ; Jade ; MT 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
Iqirvo	elafibranor tab	80 MG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; IL HIM Annual 2025 ; Jade ; NM HIM Annual 2025 ; NM Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; Topaz ; Whole Foods
Livdelzi	seladelpar lysine cap	10 MG	IL HMO Performance Annual ; 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 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
Ocaliva	Obeticholic Acid Tab 10 MG	10 MG	IL HMO Performance Annual ; 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 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
Ocaliva	Obeticholic Acid Tab 5 MG	5 MG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; 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	<table border="1"> <thead> <tr> <th>Preferred Target Agent(s)</th> <th>Non-Preferred Target Agent(s)</th> </tr> </thead> <tbody> <tr> <td>Iqirvo Livdelzi</td> <td>Ocaliva</td> </tr> </tbody> </table> <p>Initial Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of primary biliary cholangitis (PBC) AND ALL of the following: <ol style="list-style-type: none"> 1. Diagnosis has been confirmed by at least TWO of the following: <ol style="list-style-type: none"> A. There is biochemical evidence of cholestasis with an alkaline phosphatase (ALP) elevation B. ONE of the following: <ol style="list-style-type: none"> 1. Positive presence of antimitochondrial antibody (AMA) OR 2. Positive presence of other PBC-specific autoantibodies (e.g., sp100, gp210) if AMA is negative C. Histologic evidence of nonsuppurative destruction cholangitis and destruction of interlobular bile ducts AND 2. The prescriber has measured the patient's baseline alkaline phosphatase (ALP) level and total bilirubin level (prior to therapy with the requested agent) AND 3. ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. The patient has tried and had an inadequate response after at least 1 year of therapy with ursodeoxycholic acid (UDCA) (inadequate response after 1 year of treatment with UDCA is defined as ALP greater than the upper limit of normal [ULN] and/or total bilirubin greater than ULN but less than 2x ULN) AND 2. The patient will continue therapy with ursodeoxycholic acid (UDCA) in combination with the requested agent OR B. The patient has an intolerance or hypersensitivity to therapy with ursodeoxycholic acid (UDCA) OR 		Preferred Target Agent(s)	Non-Preferred Target Agent(s)	Iqirvo Livdelzi	Ocaliva
Preferred Target Agent(s)	Non-Preferred Target Agent(s)					
Iqirvo Livdelzi	Ocaliva					

Module	Clinical Criteria for Approval
	<p style="text-align: center;">c. The patient has an FDA labeled contraindication to ursodeoxycholic acid (UDCA) OR</p> <p>B. The patient has another FDA labeled indication for the requested agent AND</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 OR</p> <p>B. There is support for using the requested agent for the patient's age for the requested indication AND</p> <p>3. If the requested agent is a non-preferred agent, then ONE of the following:</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 OR</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 required] OR</p> <p>C. The patient has tried and had an inadequate response to the ONE preferred agent [chart notes required] OR</p> <p>D. ONE preferred agent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR</p> <p>E. The patient has an intolerance or hypersensitivity to ONE preferred agent [chart notes required] OR</p> <p>F. The patient has an FDA labeled contraindication to ALL preferred agent(s) [chart notes required] OR</p> <p>G. ONE preferred agent is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR</p> <p>H. ONE preferred agent is not in the best interest of the patient based on medical necessity [chart notes required] OR</p> <p>I. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE preferred agent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] AND</p> <p>4. The patient does NOT have decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy) AND</p> <p>5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND</p> <p>6. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Length of Approval:</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>The requested agent will also be approved when the following are met:</p> <p>1. The member resides in Ohio AND</p> <p>2. The plan is Fully Insured or HIM Shop (SG) AND BOTH of the following</p> <p>A. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>B. ONE of the following:</p> <p>1. The patient has another FDA labeled indication for the requested agent and route of administration OR</p>

Module	Clinical Criteria for Approval
	<p>2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR</p> <p>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]</p> <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: 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>Length of Approval:</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>Renewal Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 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] AND 2. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of primary biliary cholangitis (PBC) AND BOTH of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The requested agent will be used in combination with ursodeoxycholic acid (UDCA) OR B. The patient has an intolerance, hypersensitivity, or an FDA labeled contraindication to therapy with ursodeoxycholic acid (UDCA) AND 2. The patient has had clinical benefit with the requested agent as indicated by BOTH of the following: <ol style="list-style-type: none"> A. The patient has had an alkaline phosphatase (ALP) decrease of greater than or equal to 15% from baseline (prior to therapy with the requested agent) AND ALP is less than the upper limit of normal (ULN) AND B. The patient's total bilirubin is less than or equal to the upper limit of normal (ULN) OR B. The patient has a diagnosis other than primary biliary cholangitis AND has had clinical benefit with the requested agent AND 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 4. The patient does NOT have any FDA labeled contraindications to the requested agent

Module	Clinical Criteria for Approval
	<p>Length of Approval:</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>Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the program quantity limit OR 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication OR B. BOTH of the following: <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND 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 OR C. BOTH of the following: <ol style="list-style-type: none"> 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication <p>Length of Approval: 12 months</p>