



Cholestasis Pruritus Prior Authorization Program Summary

POLICY REVIEW CYCLE

Effective Date
09-15-2025

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
Livmarli	maralixibat chloride oral soln ; maralixibat chloride tab	10 MG ; 15 MG ; 19 MG/ML ; 20 MG ; 30 MG ; 9.5 MG/ML	M ; N ; O ; Y	N		
Bylvay ; Bylvay (pellets)	odevixibat cap ; odevixibat pellets cap sprinkle	1200 MCG ; 200 MCG ; 400 MCG ; 600 MCG	M ; N ; O ; Y	N		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Bylvay ; Bylvay (pellets)	odevixibat cap ; odevixibat pellets cap sprinkle	1200 MCG ; 200 MCG ; 400 MCG ; 600 MCG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Annual 2026 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL non-HMO Performance Full ; 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 ; Whole Foods
Livmarli	maralixibat chloride oral soln ; maralixibat chloride tab	10 MG ; 15 MG ; 19 MG/ML ; 20 MG ; 30 MG ; 9.5 MG/ML	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Annual 2025 ; HIM Annual 2026 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL non-HMO Performance Full ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Whole Foods

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval	
	TARGET AGENT(S)	PREREQUISITE AGENT(S)
	Bylvay (odevixibat) Livmarli (maralixibat)	cholestyramine naltrexone rifampicin sertraline ursodiol
	<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. BOTH of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of Alagille syndrome with pruritus (medical records required) OR B. BOTH of the following: <ol style="list-style-type: none"> 1. The patient has a diagnosis of progressive familial intrahepatic cholestasis (PFIC) with pruritus (medical records required) AND 2. The patient does NOT have a diagnosis of PFIC2 with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3) AND 2. The patient has ONE of the following: <ol style="list-style-type: none"> A. Tried and had an inadequate response to ONE prerequisite agent OR B. An intolerance or hypersensitivity to ONE prerequisite agent OR C. An FDA labeled contraindication to ALL the prerequisite agents OR B. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. If the patient has an FDA labeled indication, then ONE of the following: <ol style="list-style-type: none"> A. The patient's age is within FDA labeling for the requested indication for the requested agent OR B. There is support for using the requested agent for the patient's age for the requested indication OR B. The patient has another indication that is supported in compendia for the requested agent and route of administration AND 2. If the requested agent is Bylvay, then BOTH of the following: <ol style="list-style-type: none"> A. The patient's INR is less than 1.4 AND B. The patient has an ALT and total bilirubin that is less than 10-times the upper limit of normal (ULN) AND 3. If the requested agent is Livmarli, the patient has NOT had surgical interruption of the enterohepatic circulation of bile acid AND 	

Module	Clinical Criteria for Approval
	<p>4. The patient has a serum bile acid concentration above the upper limit of normal (ULN) AND</p> <p>5. ONE of the following:</p> <ul style="list-style-type: none"> A. The patient has NOT had a liver transplant OR B. The patient has had a liver transplant and there is support for using the requested agent post liver transplant AND <p>6. 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>7. The patient will NOT be using the requested agent in combination with another Ileal Bile Acid Transport (IBAT) inhibitor agent AND</p> <p>8. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>9. The requested quantity (dose) is within FDA labeled dosing or supported in compendia for the requested indication</p> <p>Compendia Allowed: AHFS or DrugDex 1, 2A, or 2B level of evidence</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months All other plans: 12 months</p> <p>The requested agent will also be approved when ONE of the following is met:</p> <ul style="list-style-type: none"> 1. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following: <ul style="list-style-type: none"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. The requested indication is a rare disease AND C. ONE of the following: <ul style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 2. ALL of the following: <ul style="list-style-type: none"> A. The member resides in Ohio AND B. The plan is Fully Insured or HIM Shop (SG) AND C. The patient does NOT have any FDA labeled contraindications to the requested agent AND D. ONE of the following: <ul style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 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>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p>

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	<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 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. The patient 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 will NOT be using the requested agent in combination with another Ileal Bile Acid Transport (IBAT) inhibitor agent AND 5. The patient does NOT have any FDA labeled contraindications to the requested agent AND 6. The requested quantity (dose) is within FDA labeled dosing or supported in compendia for the requested indication <p>Length of Approval:</p> <p>BCBSOK: 36 months All other plans: 12 months</p>