LOUISIANA BLUE

maralixibat oral solution (Livmarli™)

Policy # 00775
Original Effective Date: 03/14/2022
Current Effective Date: 01/13/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Alagille Syndrome

Based on review of available data, the Company may consider maralixibat oral solution (Livmarli)™‡ for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for maralixibat oral solution (Livmarli) for the treatment of cholestatic pruritus in patients with Alagille syndrome will be considered when the following criteria are met:

Initial:

- Patient has a diagnosis of cholestatic pruritis due to Alagille syndrome; AND
- Alagille syndrome diagnosis has been confirmed by genetic testing demonstrating *JAG1* or *NOTCH2* deletion or mutations; AND
- Patient is at least 3 months of age or older; AND
- Patient's serum bile acid concentration is above the upper limit of normal reference range for the reporting laboratory; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility, based on clinical trials, and will be denied as not medically necessary** if not met).*
- Patient does NOT have cirrhosis; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility, based on clinical trials, and will be denied as not medically necessary** if not met).*
- Patient does NOT have portal hypertension; AND
  *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility, based on clinical trials, and will be denied as not medically necessary** if not met).*
- Patient does NOT have a history of a hepatic decompensation event (examples include variceal hemorrhage, ascites, hepatic encephalopathy); AND

- Requested concentration is Livmarli 9.5 mg/mL; AND
- Dose of the requested medication will NOT exceed 28.5 mg per day; AND
- Dose of the requested medication will NOT exceed 380 micrograms per kilogram per day; AND
- Patient has tried and failed (e.g., intolerance or inadequate response) TWO other medications for this condition (e.g., cholestyramine, rifampin, and ursodiol) unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient will not use Livmarli in combination with odevixibat (Bylvay™)‡.

Continuation:

- Initial patient selection criteria were met; AND
- Patient does NOT have cirrhosis; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility, based on clinical trials, and will be denied as not medically necessary** if not met).*
- Patient does NOT have portal hypertension; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility, based on clinical trials, and will be denied as not medically necessary** if not met).*
- Patient does NOT have a history of a hepatic decompensation event (examples include variceal hemorrhage, ascites, hepatic encephalopathy); AND
- Requested concentration is Livmarli 9.5 mg/mL; AND
- Dose of the requested medication will NOT exceed 28.5 mg per day; AND
- Dose of the requested medication will NOT exceed 380 micrograms per kilogram per day; AND
- Patient has responded to therapy with the requested product (i.e., a decrease in serum bile acids and a decrease in pruritis); AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient will not use Livmarli in combination with odevixibat (Bylvay).

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Progressive Familial Intrahepatic Cholestasis

Based on review of available data, the Company may consider maralixibat oral solution (Livmarli) for the treatment of cholestatic pruritus in patients with progressive familial intrahepatic cholestasis (PFIC) to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for maralixibat oral solution (Livmarli) for the treatment of cholestatic pruritus in patients with progressive familial intrahepatic cholestasis will be considered when the following criteria are met:

Initial:

- Patient has a diagnosis of pruritus due to progressive familial intrahepatic cholestasis (PFIC) Types 1, 2, 3, 4 or 6; AND
  *(Note: This specific patient selection criterion is partially an additional Company requirement for coverage eligibility. Requests for Type 5 PFIC will be denied as not medically necessary** if not met).*
- Patient meets one of the following, which confirms the diagnosis of PFIC:
  - Type 1: Presence of mutations in the *ATP8B1* gene; OR
  - Type 2: Presence of mutations in the *ABCB11* gene; OR
  - Type 3: Presence of mutations in the *ABCB4* gene; OR
  - Type 4: Presence of mutations in the tight junction protein 2 gene (*TJP2*); OR
  - Type 6: Presence of mutations in the myosin 5B gene (*MYO5B*); AND
- Patient has the presence of moderate to severe pruritus (per the prescriber); AND
  *(Note: This specific patient selection criterion is partially an additional Company requirement for coverage eligibility. Requests for pruritus severity that are not considered moderate to severe will be denied as not medically necessary** if not met).*
- Patient is 12 months of age or older; AND
- Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient does NOT have a pathologic variant of the *ABCB11* gene that predicts non-function or complete absence of bile salt export pump protein (BSEP-3); AND
- Patient does NOT have cirrhosis; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient does NOT have portal hypertension; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient does NOT have a history of a hepatic decompensation event (examples include variceal hemorrhage, ascites, hepatic encephalopathy); AND

- Patient has NOT had a liver transplant; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Requested concentration is Livmarli 19 mg/mL; AND
- Dose of the requested medication will NOT exceed 38 mg per day; AND
- Dose of the requested medication will NOT exceed 570 micrograms per kilogram per dose; AND
- Patient has tried and failed (e.g., intolerance or inadequate response) BOTH GENERIC ursodeoxycholic acid AND GENERIC cholestyramine or colestipol unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient has tried and failed (e.g., intolerance or inadequate response) one of the following: GENERIC rifampin, GENERIC naltrexone, or GENERIC sertraline, unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient has tried and failed (e.g., intolerance or inadequate response) odevixibat (Bylvay) unless there is clinical evidence or patient history that suggests the use of this product will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient will not use Livmarli in combination with odevixibat (Bylvay).

Continuation:

- Patient has received an initial authorization for Livmarli; AND
- Patient does NOT have cirrhosis; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient does NOT have portal hypertension; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient does NOT have a history of a hepatic decompensation event (examples include variceal hemorrhage, ascites, hepatic encephalopathy); AND
- Patient has NOT had a liver transplant; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Requested concentration is Livmarli 19 mg/mL; AND
- Dose of the requested medication will NOT exceed 38 mg per day; AND

- Dose of the requested medication will NOT exceed 570 micrograms per kilogram per dose; AND
- Patient has responded to therapy with the requested medication (e.g., decreased pruritus and/or decrease in serum bile acids); AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient will not use Livmarli in combination with odevixibat (Bylvay).

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of maralixibat oral solution (Livmarli) when the patient has cirrhosis or portal hypertension to be **not medically necessary.****

Based on review of available data, the Company considers the use of maralixibat oral solution (Livmarli) when the patient does NOT have a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory to be **not medically necessary.****

Based on review of available data, the Company considers the use of maralixibat oral solution (Livmarli) when the patient has not tried and failed (e.g., intolerance or inadequate response) other required medications for the requested condition to be **not medically necessary.****

Based on review of available data, the Company considers the use of maralixibat oral solution (Livmarli) when the patient has Type 5 progressive familial intrahepatic cholestasis (PFIC) to be **not medically necessary.****

Based on review of available data, the Company considers the use of maralixibat oral solution (Livmarli) when the patient does NOT have pruritus that is considered to be moderate to severe to be **not medically necessary.****

Based on review of available data, the Company considers the use of odevixibat (Bylvay) when the patient has had a liver transplant to be **not medically necessary.****

Based on review of available data, the Company considers the continued use of maralixibat oral solution (Livmarli) when the patient has not responded to therapy to be **not medically necessary.****

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of maralixibat oral solution (Livmarli) when the patient selection criteria are not met (EXCEPT those denoted as **not medically necessary****) to be **investigational.***

Background/Overview

Livmarli is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 3 months of age and older and for the treatment of cholestatic pruritus in patients with progressive familial intrahepatic cholestasis (PFIC) 12 months of age and older. Livmarli is supplied as an oral solution in concentrations containing 9.5 mg or 19 mg of drug per milliliter of solution. The two strengths of Livmarli should not be substituted for one another. Special attention should be given to the accurate calculation of the dose volume of Livmarli. This is especially important for pediatric patients less than 5 years old as Livmarli oral solution contains the excipient propylene glycol. In ALGS, the 9.5mg/mL concentration should be used for treatment. The recommended dosage is 380 mcg/kg once daily, taken 30 minutes before the first meal of the day. Dosing should be started at 190 mcg/kg administered orally once daily; after one week, the dosage can be increased to 380 mcg/kg once daily, as tolerated. The maximum daily dose volume for patients above 70kg is 3 mL or 28.5 mg per day. In PFIC, the 19mg/mL concentration should be used. The recommended dosage for patients with PFIC is 570 mcg/kg twice daily 30 minutes before a meal. The starting dose is 285 mcg/kg once daily in the morning and should be increased to 285 mcg/kg twice daily, 428 mcg/kg twice daily, and then to 570 mcg/kg twice daily, as tolerated. The maximum daily dose should not exceed 38mg (4mL) per day. Refer to the package insert for complete details on dosing. The efficacy and safety of Livmarli in patients with clinically significant portal hypertension and in patients with decompensated cirrhosis have not been established. Livmarli is contraindicated in patients with prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy).

Alagille syndrome is an autosomal dominant liver disease which affects the bile acid transporters leading to chronic cholestasis and elevations of serum bile acids. This condition is identified by the presence of a mutation or deletion of the *JAG1* gene or *NOTCH2* gene. Clinical manifestations include cholestasis, pruritis, xanthomas, and jaundice. Progression of the disease can lead to fibrosis and cirrhosis. Livmarli decreases the reabsorption of bile acids from the terminal ileum. The exact mechanism of action of Livmarli on improving pruritis is unknown however it more than likely involves its mechanism of action. Other drug therapies, such as ursodiol, rifampin, and cholestyramine have been used off label for decades to treat pruritis. Ursodiol has demonstrated the

ability to decrease the advancement of liver fibrosis in related cholestatic conditions. Given the historical use of ursodiol, rifampin, and cholestyramine for cholestatic pruritis and Livmarli's primary outcome measurement of itch scores (and not outcomes data), it is reasonably appropriate to recommend a trial of off-label, yet clinically accepted, alternative medications.

PFIC is a group of rare, genetic disorders that affects bile acid transporters. There are currently 6 types of PFIC: Types 1, 2, 3, 4, 5 and 6. An in-depth analysis of each type is beyond the scope of this medical policy. Livmarli clinical studies included Types 1, 2, 3, 4, and 6 PFIC. These types of PFIC are caused by mutations in the *ATP8B1*, *ABCB11*, *ABCB4*, *TJP2*, and *MYOB5* genes, respectively. As a result of the mutations, retention of bile acids occurs within the body. Bile flow is integral for the digestion and absorption of dietary fats, vitamins, and other nutrients. Bile flow also facilitates the elimination of excess cholesterol, bilirubin, waste, and toxins from the body. Due to the retention of bile acids in the body, common clinical manifestations include cholestasis, pruritus, and jaundice. Off-label use of ursodeoxycholic acid, cholestyramine, rifampin, naltrexone, and sertraline are commonly used to alleviate symptoms associated with PFIC. A small study of patients with PFIC using ursodeoxycholic acid demonstrated improvements in liver function, hepatosplenomegaly, and pruritus for the majority of the group. European guidelines even discuss the use of ursodeoxycholic acid in this group of conditions. If pruritus is not relieved by ursodeoxycholic acid, then cholestyramine can be used to deplete the bile acid pool. Rifampin works by increasing the metabolism and excretion of pruritogens. Studies suggest that sertraline and naltrexone are also viable options for therapy in these patients. After the exhaustion of pharmacologic agents, surgical procedures to interrupt the circulation of bile acids are often successful.

In addition to Livmarli, a second ileal bile acid transporter (IBAT) inhibitor, odevixibat (Bylvay), has been approved by the Food and Drug Administration (FDA) for the treatment of these conditions. There have been no head-to-head studies comparing these two products to suggest clinical superiority; however, there are considerable differences between them in the cost of treatment of ALGS and PFIC.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Livmarli, approved in late 2021, is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 1 year of age and older. In March of 2023, the FDA label was updated to include approval for patients 3 months of age and older. In March of 2024, Livmarli was approved for the treatment of cholestatic pruritus in patients 5 years of age and older with progressive familial intrahepatic cholestasis. In July 2024, the approval for the treatment of cholestatic pruritus in patients with progressive familial intrahepatic cholestasis was expanded to include patients 12 months of age and older.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The efficacy of Livmarli in ALGS was assessed in Trial 1, which consisted of an 18-week open-label treatment period; a 4-week randomized, double-blind, placebo-controlled drug-withdrawal period; a subsequent 26-week open-label treatment period; and a long-term open-label extension period.

Thirty-one pediatric Alagille syndrome patients with cholestasis and pruritus were enrolled, with 90.3% of patients receiving at least one medication to treat pruritus at study entry. All patients had a *JAG1* mutation. Patients were administered open-label treatment with Livmarli 380 mcg/kg once daily for 13 weeks after an initial 5-week dose-escalation period; two patients discontinued treatment during this first 18 weeks of open-label treatment. The 29 patients who completed the open-label treatment phase were then randomized to continue treatment with Livmarli or receive matching placebo during the 4- week drug withdrawal period at Weeks 19-22 (n=16 placebo, n=13 Livmarli). All 29 patients completed the randomized, blinded drug withdrawal period; subsequently, patients received open-label Livmarli at 380 mcg/kg once daily for an additional 26 weeks.

Given the patients' young age, a single-item observer-reported outcome was used to measure patients' pruritus symptoms as observed by their caregiver twice daily (once in the morning and once in the evening) on the Itch Reported Outcome Instrument (ItchRO[Obs]). Pruritus symptoms were assessed on a 5-point ordinal response scale, with scores ranging from 0 (none observed or reported) to 4 (very severe). Patients were included in Trial 1 if their average pruritus score was greater than 2.0 (moderate) in the 2 weeks prior to baseline. The average of the worst daily ItchRO(Obs) pruritus scores was computed for each week. For randomized patients, the mean (SD) at baseline (pre-treatment) was 3.1 (0.5) and the mean (SD) at Week 18 (pre-randomized withdrawal period) was 1.4 (0.9). On average, patients administered Livmarli for 22 weeks maintained pruritus reduction whereas those in the placebo group who were withdrawn from Livmarli after Week 18 returned to baseline pruritus scores by Week 22. After re-entering the open-label treatment phase, both randomized treatment groups had similar mean pruritus scores by Week 28, the first week placebo patients received the full dosage of Livmarli after withdrawal. These observer-rated pruritus results are supported by similar results on patient-rated pruritus in patients 5 years of age and older who were able to self-report their itching severity.

The efficacy of Livmarli in PFIC was evaluated in one 26-week, randomized, placebo-controlled pivotal trial. Efficacy was evaluated in 64 patients with a clinical genetic confirmation of PFIC. Patients had to have an elevated serum bile acid concentration along with presence of moderate to

severe pruritus at baseline. Patients were randomized to receive Livmarli orally 570 mcg/kg (n=33) or placebo (n=31) twice daily. Most patients were on stable ursodeoxycholic acid (89.1%) or rifampicin (51.6%) therapy at baseline.

The same 5-point ordinal scratching scale used in Trial 1 was also used in Trial 2. Scratching scores were observed and reported by the patients' caregiver twice daily (once in the morning and once in the evening). Patients treated with Livmarli demonstrated greater improvement in pruritus compared with placebo.

References

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9. Kohut T, Gilbert MA, Loomes KM. Alagille Syndrome: a focused review on clinical features, genetics, and treatment. Semin Liver Dis. 2021;41(4):525-537.

Policy History

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02/03/2022	Medical Policy Committee review
02/09/2022	Medical Policy Implementation Committee approval. New policy.
02/02/2023	Medical Policy Committee review
02/08/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/02/2023	Medical Policy Committee review
11/08/2023	Medical Policy Implementation Committee approval. Updated criteria to reflect newest FDA label update for approval in patients 3 months of age and older.

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07/02/2024	Medical Policy Committee review
07/10/2024	Medical Policy Implementation Committee approval. Added a new FDA approved indication PFIC, included relevant criteria and background information. Updated ALGS criteria to clarify that doses above the labeled maximum dose are not covered. Updated denial reasoning for ALGS criterion regarding the history of hepatic decompensation to investigational and criterion requiring serum bile acid concentrations above the upper limit of normal to not medically necessary.
12/05/2024	Medical Policy Committee review
12/11/2024	Medical Policy Implementation Committee approval. Updated the age requirement for the treatment of cholestatic pruritus in patients with PFIC to include patients 12 months of age and older per the updated FDA package insert. Added new strength, 19 mg/mL solution, with relevant dosing criteria and background information.

Next Scheduled Review Date: 12/2025

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.