



Livmarli® (maralixibat)
Effective 11/01/2022

Plan	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Livmarli® (maralixibat) is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of cholestatic pruritus in patients ≥1 years of age with Alagille syndrome.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

1. Diagnosis of Alagille syndrome
2. Genetic testing documenting JAG1 or NOTCH2 deletion or genetic testing confirming mutation in GAA gene
3. Member has moderate to severe pruritus caused by cholestasis
4. Prescriber is a specialist (hepatologist, gastroenterologist, or Alagille syndrome specialist) or consult notes from a specialist are provided
5. Member is ≥1 year of age
6. Paid claim or physician documentation of inadequate response or adverse reaction to **TWO**, or contraindication to **ALL** of the following
 - a. bile acid sequestrants (e.g., cholestyramine or colestipol)
 - b. rifampin
 - c. ursodiol
 - d. naltrexone
 - e. sertraline

7. Appropriate dosing

Continuation of Therapy

Reauthorizations requires physician documentation of continuation of therapy and positive response to therapy as evidenced by improvement in severity of pruritus.

Limitations

1. Initial approvals will be granted for 6 months.
2. Reauthorizations will be granted for 12 months.

Drug	Adult and Pediatric Dose (≥1 year of age)
Livmarli® (maralixibat) Oral solution: 9.5 mg/mL	<u>Cholestatic pruritus due to Alagille syndrome:</u> Solution: initial, 190 µg/kg PO QD for seven days; maximum dose of 14.25 mg maintenance, 380 µg/kg PO QD, maximum dose of 28.5 mg

PO=orally, QD=once daily

References

1. Livmarli® (maralixibat) [package insert on the internet]. Foster City (CA): Mirum Pharmaceuticals; 2021 Sept.
2. Livmarli® (maralixibat) product eDossier. [AMCP Formulary Dossier]. Oct 2021. Version 4.1. Mirum Pharmaceuticals, Inc. Accessed via secure log in to the AMCP eDossier System (<https://amcp.edossiers.com>) on 01/07/2022.
3. National Organization for Rare Disorders. Alagille Syndrome [webpage on the internet]. Danbury (CT): National Organization for Rare Disorders; (2020) [cited 2022 Jan 25]. Available from: <https://rarediseases.org/rare-diseases/alagille-syndrome/>.
4. Poupon R, Chopra S. Pruritus associated with cholestasis. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2022 [cited 2022 Jan 25]. Available from <http://www.uptodate.com/utd/index.do>.
5. Ayoub MD, Kamath BM. Alagille Syndrome: Diagnostic Challenges and Advances in Management. Diagnostics (Basel). 2020 Nov 6;10(11):907. PMID: 33172025.
6. Gonzales E, Hardikar W, Stormon M, Baker A, Hierro L, Gliwicz D, et al. Efficacy and safety of maralixibat treatment in patients with Alagille syndrome and cholestatic pruritus (ICONIC): a randomised phase 2 study. Lancet. 2021 Oct 30;398(10311):1581-1592. PMID: 34755627.
7. Mirum Pharmaceuticals Announces Partnership with EVERSANA to Support Launch and Commercialization of Maralixibat for Alagille Syndrome in the United States [press release on the internet]. Foster City (CA): EVERSANA; 2020 Oct 15 [cited 2022 Jan 25]. Available from: <https://www.eversana.com/2020/10/15/mirum-pharmaceuticals-announces-partnership-with-eversana-to-support-launch-and-commercialization-of-maralixibat-for-alagille-syndrome-in-the-united-states/>.
8. U.S. FDA Approves Livmarli (Maralixibat) as the First and Only Approved Medication for the Treatment of Cholestatic Pruritus in Patients with Alagille Syndrome One Year of Age and Older [press release on the internet]. Foster City (CA): Mirum Pharmaceuticals; 2021 Sep 29 [cited 2022 Jan 25]. Available from: <https://ir.mirumpharma.com/news-releases/news-release-details/us-fda-approves-livmarli-maralixibat-first-and-only-approved>.
9. Albireo. Efficacy and Safety of Odevixibat in Patients with Alagille Syndrome (ASSERT). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000 – [cited 2022



jan 25]. Available from: <https://clinicaltrials.gov/ct2/show/NCT04674761> NLM Identifier: NCT04674761

Review History

09/21/2022 – Reviewed and Created for September P&T. Matched MH criteria. Effective 11/1/22.

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