

Livmarli (maralixibat)
Effective 05/01/2022

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	N/A		
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 indicated for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 1 year of age and older.

Coverage Guidelines

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

OR

Authorization may be granted if the member meets all following criteria and documentation has been submitted:

Livmarli® (maralixibat)

1. The member has a diagnosis of Alagille syndrome (ALGS) confirmed by ONE of the following:
 - a. Bile duct paucity
 - b. THREE of the five major clinical features of ALGS:
 - i. Cholestasis
 - ii. Cardiac defect (e.g., stenosis of the peripheral pulmonary artery and its branches)
 - iii. Skeletal abnormality (e.g., butterfly vertebrae)
 - iv. Ophthalmologic abnormality (e.g., posterior embryotoxon)
 - v. Characteristic facial features (e.g., triangular-shaped face with a broad forehead and a pointed chin, bulbous tip of the nose, deeply set eyes, and hypertelorism)
2. Member is \geq 1 year of age
3. Member has evidence of cholestasis defined as the presence of ONE or more of the following:

- a. Total serum bile acid greater than 3 times the upper limit of normal (ULN) for age
 - b. Conjugated bilirubin greater than 1 mg/dL
 - c. Fat soluble vitamin deficiency otherwise unexplainable
 - d. Gamma-glutamyl transferase (GGT) greater than 3 times ULN for age
 - e. Intractable pruritis explainable only by liver disease
4. The member does not have a history or presence of other concomitant liver disease
 5. The member has not received a liver transplant

Continuation of Therapy

Reauthorization by physician documented of positive clinical response as evidence by improvement in pruritis.

Limitations

1. Initial approvals will be granted for: 6 months
2. Reauthorizations will be granted for: 12 months
3. The following quantity limits apply:

Livmarli 9.5mg/mL	90mL per 30 days
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References

1. Livmarli [package insert]. Foster City, CA: Mirum Pharmaceuticals, Inc.; September 2021.
2. Spinner NB, Gilbert MA, Loomes KM, Krantz ID. Alagille syndrome. GeneReviews® [Internet]. December 12, 2019. Last updated December 12, 2019. Accessed October 19, 2021. https://www.ncbi.nlm.nih.gov/books/NBK1273/#__NBK1273_dtls__.
3. Genetic and Rare Diseases Information Center. Alagille syndrome. Rare Disease Database. <https://rarediseases.info.nih.gov>. Updated October 20, 2017. Accessed October 18, 2021.
4. National Organization for Rare Disorders (NORD). Alagille syndrome. Rare Disease Database. <https://rarediseases.org>. Published 2020. Accessed October 18, 2021.

Review History

03/16/2022 – Created for March P&T Effective 05/01/2022.

