Mass General Brigham
Health Plan

Livmarli (maralixibat)
Effective 05/01/2022

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
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

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.