Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	December 8, 2021 March 16, 2023, December 20, 2023

ILEAL BILE ACID TRANSPORTER INHIBITOR AGENTS
BYLVAY™ (odevixibat) and LIVMARLI™ (maralixibat)

LENGTH OF AUTHORIZATION: Up to 6 months

INITIAL REVIEW CRITERIA:

- Patient has an elevated serum bile acid concentration.
- Patient experiences persistent pruritus.
- Patient has trial and failure or contraindication to at least 1 pruritis treatment (e.g., ursodiol, cholestyramine, antihistamine).
- Patient has baseline liver function and fat-soluble vitamin tests and is monitored during treatment.

Bylvay

- Patient must be ≥ 3 months of age.
- Patient must have a diagnosis of pruritus with progressive familial intrahepatic cholestasis (PFIC) confirmed by a genetic test.

Livmarli

- Patient must be ≥ 3 months of age.
- Patient must have a diagnosis of cholestatic pruritus in patients with Alagille syndrome (ALGS) confirmed by a genetic test.

CONTINUATION OF THERAPY:

- Patient met initial review criteria.
- Documentation of improved clinical response.
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Bylvay is available as 200 mcg and 600 mcg oral pellets and 400 mcg and 1,200 mcg capsules.
- Livmarli is available as 9.5 mg/mL oral solution.