Odevixibat (Bylvay) and Maralixibat (Livmarli)

Coverage Criteria:
Bylvay and Livmarli are reserved for patients meeting the following criteria:

1. Medication has been prescribed by or in consultation with a hepatologist; and,
2. Patient has uncontrolled cholestatic pruritus; and,
3. Patient has been diagnosed with one of the following:
    a. For Bylvay:
        i. diagnosed with progressive familial intrahepatic cholestasis (PFIC) as confirmed by genetic testing, and patient does not have PFIC type 2 with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3); or,
        ii. diagnosed with Alagille Syndrome as confirmed by genetic testing; or,
    b. For Livmarli: diagnosed with Alagille Syndrome as confirmed by genetic testing; and,
4. Patient has tried and failed (or has medical contraindications to) all of the following therapies alone or in combination for a duration of at least 12 weeks each:
    a. Antihistamines; and,
    b. Ursodiol; and,
    c. Cholestyramine; and,
    d. Rifampin; and,
    e. Naltrexone; and,
    f. Sertraline or phenobarbital; and,
5. Patient has been evaluated by a liver transplant center for liver transplant candidacy; and,
6. Prescriber attests to monitoring of liver function (ALT, AST, total and direct bilirubin, INR) during treatment with the medication; and,
7. Bylvay and Livmarli will not be used concurrently; and,
8. For Bylvay in Alagille syndrome: Patient has a medication contraindication to use of Livmarli; and,
9. Medication has been prescribed within the FDA-approved dosing regimen.

Coverage Duration:
Initial authorization will be granted for a 3 months duration.
Reauthorizations will be granted for a 6 months duration.

Renewal Criteria:

1. Patient continues to meet the criteria above; and,
2. Patient has been seen within the past 6 months by the prescribing provider; and,
3. Chart notes must be submitted showing the patient has had a clinically significant reduction in pruritus; and,
4. Medication has been prescribed within the FDA-approved dosing regimen.

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