

**BYLVAY
(odevixibat)**

Pre - PA Allowance

None

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Pruritus associated with Progressive Familial Intrahepatic Cholestasis (PFIC)
 - a. 3 months of age or older
 - b. **NO** PFIC type 2 with ABCB11 variants causing non-functional or complete absence of bile salt export pump protein
2. Cholestatic pruritus associated with Alagille syndrome (ALGS)
 - a. 12 months of age or older
 - b. Diagnosis has been confirmed by **ONE** of the following:
 - i. Genetic testing (e.g., JAGGED1 mutation)
 - ii. Patient has bile duct paucity **AND** at least 3 major clinical features of ALGS (e.g., cholestasis, cardiac defect, skeletal abnormality, ophthalmic abnormality, or characteristic facial features)

AND ALL of the following:

1. **NO** cirrhosis, clinically significant portal hypertension, or hepatic decompensation
2. Inadequate treatment response, intolerance, or contraindication to **ONE** of the following:
 - a. Cholestyramine
 - b. Rifampin
 - c. Ursodeoxycholic acid (UDCA)
3. Patient has had baseline liver function tests (LFTs) and serum fat-soluble vitamin (FSV) levels performed
4. Prescriber agrees to monitor LFTs and serum FSV levels during treatment

Prior - Approval Limits

Quantity 7,200 mcg (7.2 mg) per day

Duration 12 months

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Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Pruritus associated with Progressive Familial Intrahepatic Cholestasis (PFIC)
 - a. 3 months of age or older
2. Cholestatic pruritus associated with Alagille syndrome (ALGS)
 - a. 12 months of age or older

AND ALL of the following:

1. Improvement in pruritus symptoms, or observed improvement in scratching
2. **NO** cirrhosis, clinically significant portal hypertension, or hepatic decompensation
3. Prescriber agrees to monitor LFTs and serum FSV levels during treatment

Prior – Approval *Renewal* Limits

Same as above