Pharmacy Drug Policy Checklist

POLICY NAME	Bylvay (odevixibat)	POLICY #	3176P

Criteria

Coverage Criteria for Pruritus due to Familial Intrahepatic Cholestasis

- ☐ **1.1** Diagnosis of pruritus (itching) due to progressive familial intrahepatic cholestasis (PFIC)
  - Diagnosis confirmed by genetic testing showing biallelic pathogenic mutations in the ATP8B1 (ie, PFIC1) or ABCB11 (ie, PFIC2) genes
- ☐ **1.2** Member has cholestasis, as indicated by one of the following:
  - Total serum bile acid >3 × upper limit of normal (ULN) for age
  - Conjugated bilirubin >2 mg/dL
  - Fat soluble vitamin deficiency that is otherwise unexplainable
  - Gamma Glutamyl Transferase (GGT) >3 × ULN for age
  - Intractable pruritus explainable only by liver disease
- ☐ **1.3** Age 3 months or older
- ☐ **1.4** Prescribed by or in consultation with a hepatologist (liver doctor)
- ☐ **1.5** Documented concurrent use or previous trial and failure, intolerance or contraindication ursodiol and cholestyramine
- ☐ **1.6** Review of chart notes documenting diagnosis and confirming that the patient has met all of the above requirements for treatment with Bylvay by both a pharmacist and medical director

Coverage Criteria for Pruritus due to Alagille Syndrome

- ☐ **2.1** Diagnosis of moderate to severe pruritus due to Alagille syndrome (ALGS)
  - Diagnosis of ALGS confirmed by genetic testing showing pathogenic variants in the JAG1 or NOTCH2 genes
- ☐ **2.2** Member has cholestasis, as indicated by one of the following:
  - Total serum bile acid >3 × upper limit of normal (ULN) for age
  - Conjugated bilirubin >2 mg/dL
  - Fat soluble vitamin deficiency that is otherwise unexplainable
  - Gamma Glutamyl Transferase (GGT) >3 × ULN for age
  - Intractable pruritus explainable only by liver disease
- ☐ **2.3** Age 12 months or older
- ☐ **2.4** Prescribed by or in consultation with a hepatologist (liver doctor)

☐ **2.5** Documented trial and failure, contraindication or intolerance to TWO of the following:

- Ursodiol
- Rifampin
- Cholestyramine
- Sertraline
- Naltrexone (not for pediatric patients)

☐ **2.6** Review of chart notes documenting diagnosis and confirming that the patient has met all of the above requirements for treatment with Bylvay by both a pharmacist and medical director

Exclusion Criteria – Any of the following prevents coverage

☐ **3.1** Genetic testing indicates PFIC with ABCB11 variants encoding for non-function or absence of BSEP-3

☐ **3.2** Pregnancy

☐ **3.3** Chronic diarrhea requiring consistent fluid or nutritional intervention

☐ **3.4** History of liver transplant or biliary diversion surgery within the past 6 months

☐ **3.5** Evidence of decompensated cirrhosis

☐ **3.6** Concurrent use with Livmarli