

Prior Authorization Criteria
Bylvay (odevixibat)

All requests for Bylvay (odevixibat) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Coverage may be provided with a diagnosis of **cholestatic pruritis** caused by **progressive familial intrahepatic cholestasis (PFIC) or Alagille syndrome (ALGS)** and the following criteria is met:

- Member must be ≥ 3 months old
- Must be prescribed by or in consultation with a hepatologist or gastroenterologist
- Must provide documentation of BOTH of the following:
 - Genetic testing confirming the diagnosis
 - Moderate to severe pruritus
- Must provide documentation showing the member has tried and failed or had an intolerance or contraindication to ursodeoxycholic acid (Ursodiol)
- Must provide documentation showing the member has tried and failed or had an intolerance or contraindication to ONE of the following for symptomatic relief of pruritis:
 - Bile acid sequestrants (i.e. cholestyramine, colesevelam, or colestipol)
 - Rifampicin
 - Antihistamine
- Must provide baseline documentation of BOTH of the following:
 - Liver function tests
 - Fat-soluble vitamin levels
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- **Initial Duration of Approval:** 3 months
- **Reauthorization criteria**
 - Must submit LFTs within past 3 months
 - Must submit fat-soluble vitamin levels within past 3 months
 - Documentation of improvement of pruritus OR dosing plan for continued use if no documented clinical benefit
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

BYLVAY (ODEVIXIBAT) PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Wholecare Pharmacy Services. **FAX:** (888) 245-2049

If needed, you may call to speak to a Pharmacy Services Representative. **PHONE:** (800) 392-1147 Mon – Fri 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Member ID:	Member weight: Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:
Directions:	Quantity: Refills:
Is the member currently receiving requested medication? <input type="checkbox"/> Yes <input type="checkbox"/> No Date Medication Initiated:	

Billing Information

This medication will be billed: <input type="checkbox"/> at a pharmacy OR <input type="checkbox"/> medically, JCODE: _____
Place of Service: <input type="checkbox"/> Hospital <input type="checkbox"/> Provider's office <input type="checkbox"/> Member's home <input type="checkbox"/> Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:
Has genetic testing been completed to confirm the diagnosis? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Is moderate to severe pruritis present? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Have baseline LFTs been checked? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Have baseline fat-soluble vitamin levels been checked? <input type="checkbox"/> Yes <input type="checkbox"/> No	
What has been tried? Check all that apply and provide the information below.	
<input type="checkbox"/> Ursodiol	<input type="checkbox"/> Bile acid sequestrant (e.g. cholestyramine, colestipol)
<input type="checkbox"/> Rifampin	<input type="checkbox"/> Antihistamine

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Have LFT's been checked within the past 3 months? <input type="checkbox"/> Yes <input type="checkbox"/> No
Have fat-soluble vitamin levels been checked within the past 3 months? <input type="checkbox"/> Yes <input type="checkbox"/> No
Has the member experienced an improvement of pruritis with treatment? <input type="checkbox"/> Yes <input type="checkbox"/> No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date