HIGHMARK HEALTH OPTIONS

Updated: 04/2025
DMMA Approved: 04/2025

Request for Prior Authorization for Bylvay (odevixibat)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

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.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

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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 Health Options Pharmacy Services. **FAX: (855) 476-4158**
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (844) 325-6251 Mon – Fri 8 am to 7 pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
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? ☐ Yes ☐ No	Date Medication Initiated:	

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____
Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ 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? ☐ Yes ☐ No
Is moderate to severe pruritis present? ☐ Yes ☐ No
Have baseline LFTs been checked? ☐ Yes ☐ No
Have baseline fat-soluble vitamin levels been checked? ☐ Yes ☐ No
What has been tried? Check all that apply and provide the information below.

☐ Ursodiol ☐ Bile acid sequestrant (e.g. cholestyramine, colesevelam, colestipol)
☐ Rifampin ☐ 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? ☐ Yes ☐ No
Have fat-soluble vitamin levels been checked within the past 3 months? ☐ Yes ☐ No
Has the member experienced an improvement of pruritis with treatment? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date