HIGHMARK WHOLECARE

Updated: 07/2023
PARP Approved: 08/2023

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 **progressive familial intrahepatic cholestasis (PFIC)** and the following criteria is met:

- Member must be ≥ 3 months old
- Must be prescribed by or in consultation with a hepatologist
- 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 BOTH of the following:
  - Bile acid sequestrants (i.e. cholestyramine, colesevelam, or colestipol)
  - Ursodiol
- 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
  - Must provide 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.

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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 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? ☐ Yes ☐ No	Date Medication Initiated:	

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 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.
☐ Bile acid sequestrant (e.g. cholestyramine, colesevelam, colestipol)
☐ Rifampin

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