

Prior Authorization Criteria
Bylvay (odevixibat)

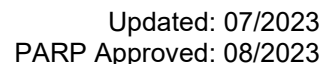
All requests for Bylvay (odevixibat) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

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.



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

PROVIDER INFORMATION

MEMBER INFORMATION

REQUESTED DRUG INFORMATION

Billing Information

Place of Service Information

MEDICAL HISTORY (Complete for ALL requests)

CURRENT or PREVIOUS THERAPY

REAUTHORIZATION

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date