

**Bylvay (odevixibat)**  
**Effective 05/01/2022**

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Medical and Specialty Medications</b>		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
<b>Exceptions</b>	<b>Non-Specialty Medications</b>		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029

### Overview

Bylvay (odevixibat) is indicated for the treatment of pruritis in patients  $\geq 3$  months of age with progressive familial intrahepatic cholestasis (PFIC). Limitations of use: May not be effective in PFIC type 2 patients with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3).

### Coverage Guidelines

Authorization may be reviewed for members new to the plan who are currently receiving treatment with the requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs

#### OR

Authorization may be granted if the member meets all following criteria and documentation has been submitted:

### Bylvay® (odevixibat)

1. The member has a diagnosis of progressive familial intrahepatic cholestasis (PFIC)
2. Genetic testing does not indicate PFIC type 2 with ABCB11 variants encoding for nonfunction or absence of BSEP-3
3. The member is  $\geq 3$  months of age
4. The medication is being prescribed by or in consultation with a hepatologist, gastroenterologist or a provider who specializes in PFIC
5. Presence of pruritis

### Continuation of Therapy

Reauthorization by physician documented of positive clinical response as evidence by improvement in severity of pruritis

### Limitations

1. Initial approvals and reauthorizations will be granted for: 12 months
2. The following quantity limits apply:

Bylvay 400mcg and 1200mcg oral capsule	60 capsules per 30 days
Bylvay (pellets) 200mcg oral capsule sprinkles	60 capsules per 30 days
Bylvay (pellets) 600mcg oral capsule sprinkles	30 capsules per 30 days

**References**

1. Bylvay (odevixibat) [prescribing information]. Boston, MA: Albireo Pharma Inc; July 2021.

**Review History**

03/16/2022 – Created for March P&T Effective 05/01/2022.

