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

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| **Plan** | ☐ MassHealth<br>☐ MH UPPL<br>☒Commercial/Exchange | **Program Type** | ☒ Prior Authorization<br>☒ Quantity Limit<br>☐ Step Therapy |
| **Benefit** | ☒ Pharmacy Benefit<br>☐ Medical Benefit (NLX) | | |
| **Specialty Limitations** | This medication has been designated specialty and must be filled at a contracted specialty pharmacy. | | |
| **Contact Information** | **Specialty Medications** | | |
| | All Plans | Phone: 866-814-5506 | Fax: 866-249-6155 |
| | **Non-Specialty Medications** | | |
| | MassHealth | Phone: 877-433-7643 | Fax: 866-255-7569 |
| | Commercial | Phone: 800-294-5979 | Fax: 888-836-0730 |
| | Exchange | Phone: 855-582-2022 | Fax: 855-245-2134 |
| | **Medical Specialty Medications (NLX)** | | |
| | All Plans | Phone: 844-345-2803 | Fax: 844-851-0882 |
| **Exceptions** | | | |

## Overview
Bylvay (odevixibat) is indicated for the treatment of pruritis in patients ≥ 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 AllWays Health Partners 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 ≥ 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:

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| 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

## Disclaimer
AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.