allways HEALTH PARTNERS

Bylvay (odevixibat)
Effective 05/01/2022

Plan	☒ MassHealth ☐ MH UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ 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. Presence of moderate to severe pruritis
5. No evidence of portal hypertension or decompensated cirrhosis
6. No history of liver transplant
7. No history of biliary diversion surgery within the past 6 months
8. Inadequate response, adverse reaction, or contraindication to ursodiol 30mg/kg/day

9. ONE Of the following
    a. Inadequate response or adverse reaction to one of the following:
        i. Cholestyramine 4 g/day
        ii. Rifampin 10 mg/kg/day
    b. Contraindication to both of the following
        i. Cholestyramine 4 g/day
        ii. Rifampin 10 mg/kg/day
10. Member's current weight
11. Appropriate dosing

Continuation of Therapy
Reauthorization by physician will infer positive response to therapy.

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

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.