

Bylvay (odevixibat)
Effective 05/01/2022

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	N/A		
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	N/A		

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.

