Pharmacy Policy Bulletin

Title: Odevixibat (Bylvay™)

Policy #: Rx.01.254

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **Odevixibat (Bylvay™)** as provided under the member's prescription drug benefit.

Description:

Progressive familial intrahepatic cholestasis is a group of rare genetic inherited disorders which are caused by defect in bile secretion and present with intrahepatic cholestasis, usually in infancy and childhood. This disorder causes a progressive liver disease and can lead to cirrhosis and end-stage liver disease. The common symptom in patients with progressive familial intrahepatic cholestasis is severe and debilitating pruritus.

Odevixibat is a reversible inhibitor of the ileal bile acid transporter (IBAT). It decreases the reabsorption of bile acids (primarily the salt forms) from the terminal ileum. Although the complete mechanism by which odevixibat improves pruritus in patients with progressive familial intrahepatic cholestasis.is unknown, it may involve inhibition of the IBAT.

BylvayTM (odevixibat) is indicated for the treatment of pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis.

Policy:

INITIAL CRITERIA Odevixibat (Bylvay™) is approved when ALL of the following are met:

1. Diagnosis of pruritus associated with progressive familial intrahepatic cholestasis (PFIC); and
2. Confirmed molecular diagnosis of PFIC type 1, 2, or 3; and
3. Member is 3 months of age or older; and
4. Prescribed dose is consistent with FDA-approved package labeling and does not exceed a total daily dose of 6mg; and
5. Prescribed by or in consultation with a hepatologist

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA Odevixibat (Bylvay™) is re-approved when BOTH of the following are met:

1. Documentation of positive clinical response to therapy (e.g., improvement in pruritus symptoms); and
2. Prescribed dose is consistent with FDA-approved package labeling and does not exceed a total daily dose of 6mg

Reauthorization duration: 2 years

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Srivastava A. Progressive familial intrahepatic cholestasis. J Clin Exp Hepatol. 2014;4(1):25-36. doi:10.1016/j.jceh.2013.10.005. Accessed January 13, 2022.

Bylvay™ (odevixibat) [package insert]. Boston, MA: Albireo Pharma, Inc.; July 2021. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215498s000lbl.pdf?utm_medium=email&utm_source=govdelivery. Accessed January 13, 2022.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Bylvay™	odevixibat

Cross References:

Rx.01.33 Off Label Use

Policy Version Number:	1.00
P&T Approval Date:	December 09, 2021
Policy Effective Date:	April 01, 2022
Next Required Review Date:	December 09, 2022