

PHARMACY POLICY STATEMENT

North Carolina Marketplace

DRUG NAME	Bylvay (odevixibat)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Bylvay, approved by the FDA in July 2021, is indicated for the treatment of pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC). It is the first drug approved for PFIC and is available as oral pellets or capsules, taken once daily.

PFIC is an ultra-rare group of genetic disorders that disrupt bile formation in the liver. It usually presents during infancy and is characterized by cholestasis, jaundice, and intense itching. Most patients will eventually require

DATE	ACTION/DESCRIPTION
11/17/2021	New policy for created for Bylvay.
06/27/2023	Added indication for Alagille Syndrome.

References:

1. Bylvay [prescribing information]. Albireo Pharma, Inc.; 2023.
2. Baumann U, Sturm E, Lacaille F, et al. Effects of odeixibat on pruritus and bile acids in children with cholestatic liver disease: Phase 2 study. *Clin Res Hepatol Gastroenterol*. 2021;45(5):101751. doi:10.1016/j.clinre.2021.101751
3. Deeks ED. Odeixibat: First Approval [published correction appears in *Drugs*. 2021 Sep 23;:].