UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1367-4
Program	Prior Authorization/Notification
Medication	Bylvay™ (odevixibat)
P&T Approval Date	9/2021, 9/2022, 8/2023, 8/2024
Effective Date	11/1/2024

1. Background:

Bylvay (odevixibat) is an ileal bile acid transporter inhibitor indicated for the treatment of pruritis in patients aged 3 months or older with progressive familial intrahepatic cholestasis (PFIC). Bylvay is also indicated for the treatment of pruritis in patients 12 months of age and older with Alagille syndrome (ALGS).

Limitation of Use:
Bylvay may not be effective in a subgroup of PFIC type 2 patients with specific ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3).

2. Coverage Criteria[a]:

A. Progressive Familial Intrahepatic Cholestasis

1. **Initial Authorization**

a. **Bylvay** will be approved based upon **both** of the following criteria:

(1) Diagnosis of progressive familial intrahepatic cholestasis (PFIC)

-AND-

(2) Patient is experiencing pruritus associated with PFIC.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Bylvay** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Bylvay therapy

Authorization will be issued for 12 months.

B. Alagille Syndrome

1. **Initial Authorization**

a. **Bylvay** will be approved based upon **both** of the following criteria:

(1) Diagnosis of Alagille syndrome (ALGS).

-AND-

(2) Patient is experiencing pruritus associated with ALGS.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Bylvay** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Bylvay therapy

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. Reference:

1. Bylvay™ [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; February 2024.

Program	Prior Authorization/Notification - Bylvay™ (odevixibat) Notification
Change Control	
9/2021	New program
9/2022	Annual review with no changes to criteria. Added state mandate footnote.
8/2023	Added coverage criteria for new ALGS indication. Updated reference.
8/2024	Annual review. Updated initial authorization durations to 12 months. Updated background and reference.