Reference number(s)
4862-A

SPECIALTY GUIDELINE MANAGEMENT

BYLVAY (odevixibat)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Bylvay is indicated for the treatment of pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC).

Limitations of Use: Bylvay may not be effective in PFIC type 2 patients with ABCB11 variants resulting in nonfunctional or complete absence of bile salt export pump protein (BSEP-3).

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. Initial requests: Genetic testing results confirming a diagnosis of progressive familial intrahepatic cholestasis (PFIC) type 1, 2, or 3.
B. Continuation requests: Chart notes or medical records documenting a benefit from therapy (e.g., improvement in pruritis).

III. EXCLUSIONS

Coverage will not be provided for members who have PFIC type 2 with variants in the ABCB11 gene that predict non-functional or complete absence of bile salt export pump protein (BSEP-3).

IV. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a hepatologist.

V. CRITERIA FOR INITIAL APPROVAL

Pruritus in progressive familial intrahepatic cholestasis (PFIC)
Authorization of 6 months may be granted for treatment of pruritis in progressive familial intrahepatic cholestasis (PFIC) when all of the following criteria are met:
A. Member has a confirmed molecular diagnosis of PFIC type 1, 2, or 3
B. Member does not have any other concomitant liver disease (e.g., biliary atresia, benign recurrent intrahepatic cholestasis [BRIC], liver cancer, alternate non-PFIC related etiology of cholestasis)

C. Member has not received a liver transplant
D. Member is 3 months of age or older.

VI. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for all members (including new members) requesting continuation of therapy when the member is experiencing benefit from therapy (e.g., improvement in pruritis).

VII. REFERENCES

1. Bylvay [package insert]. Boston, MA: Albireo Pharma, Inc.; July 2021.