Clinical Policy Title:	odevixibat
Policy Number:	RxA.698
Drug(s) Applied:	Bylvay™
Original Policy Date:	08/18/2021
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All line of business

Background

Odevixibat (Bylvay™) is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC).

Limitation of use: Bylvay™ 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).

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
odevixibat (Bylvay™)	Pruritus with PFIC	40 mcg/kg once daily in the morning with a meal. If there is no improvement in pruritus after 3 months, the dosage may be increased in 40 mcg/kg increments up to 120 mcg/kg once daily not to exceed a total daily dose of 6 mg.	6 mg/day.

Dosage Forms

- Oral pellets: 200 mcg, 600 mcg.
- Capsules: 400 mcg, 1200 mcg.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Pruritus with PFIC (must meet all):

1. Confirmed diagnosis of PFIC with molecular genetic testing;
2. Presence of moderate to severe pruritus;
3. Age ≥ 3 months of age;
4. Prescribed by or in consultation with a hepatologist or gastroenterologist;
5. Molecular genetic testing does not indicate PFIC type 2 with ABCB11 variants encoding for nonfunction or absence of BSEP-3;
6. Member has no history of liver transplant or biliary diversion surgery within past 6 months;
7. Member does not have had experienced any prior events of hepatic decompensation;
8. Concurrent or previous use of ursodiol;
9. Maximum dose does not exceed 6 mg orally once daily.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Pruritus with PFIC (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. Documentation of improvement in pruritis and reduction in serum bile acid acid to ≤ 70 µmol/L;
4. If request is for a dose increase, dose does not exceed 6 mg orally once daily.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
IBAT: Ileal bile acid transporter
PFIC: progressive familial intrahepatic cholestasis
BSEP: bile salt export pump

APPENDIX B: Therapeutic Alternatives
Not applicable.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Obtain baseline liver tests and monitor during treatment. Dose reduction or treatment interruption may be required if abnormalities occur. For persistent or recurrent liver test abnormalities, consider treatment discontinuation.
- Treat dehydration. Treatment interruption or discontinuation may be required for persistent diarrhea.
- Obtain baseline levels and monitor during treatment. Supplement if deficiency is observed. If Fat- Soluble Vitamin (FSV) deficiency persists or worsens despite FSV supplementation, discontinue treatment.

References

1. Bylvay™ prescribing information. Boston, MA: Albireo Pharma; July 2021. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=151f1d3e-2bf4-47ce-b1be-a892de3258fa&type=display . Accessed August 18, 2021.
2. Bylvay™, IPD Analytics RxInsights_New Drug Review_Bylvay™_08 2021. Accessed with subscription at: https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=Bylvay . Accessed August 18, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	08/18/2021	09/14/2021