Clinical Policy Title:	odevixibat
Policy Number:	RxA.698
Drug(s) Applied:	Bylvay™
Original Policy Date:	08/18/2021
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All line of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Pruritus with PFIC (must meet all):

1. Confirmed diagnosis of Progressive Familial Intrahepatic Cholestasis with molecular genetic testing;
2. Serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory;
3. Presence of moderate to severe pruritus;
4. Molecular genetic testing does not indicate PFIC type 2 with ABCB11 variants encoding for nonfunction or absence of BSEP-3;
5. Trial and failure at least two systemic medications for progressive familial intrahepatic cholestasis (e.g., cholestyramine, rifampicin, ursodiol), unless contraindicated or clinically significant effects are experienced.

Approval Duration

All lines of business (except Medicare): 6 months

B. Pruritus with ALGS (must meet all):

1. Diagnosis of genetically confirmed ALGS-associated pruritus.

Approval Duration

All lines of business (except Medicare): 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All lines of business (except Medicare): 12 months

References

1. Gunaydin M, Bozkurter Cil AT. Progressive familial intrahepatic cholestasis: diagnosis, management, and treatment. *Hepat Med*. 2018;10:95-104. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6136920/. Accessed August 28, 2024.
2. Long term safety & efficacy study evaluating the effect of A4250 in children with PFIC (PEDFIC 2). ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT03659916. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	08/18/2021	09/14/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.9: Updated to include new criteria pertaining to indication PFIC Drug-induced pruritus has been ruled out. 2. References were reviewed and updated.	4/22/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria I.A.2.: Added "Serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory." 2. Initial Approval Criteria I.A: Removed "Member has no history of liver transplant or biliary diversion surgery within past 6 months, "No clinical evidence of decompensated cirrhosis". 3. Initial Approval Criteria I.A.7: Added "Trial and failure at least two systemic medications for progressive familial intrahepatic cholestasis (e.g., cholestyramine, rifampicin, ursodiol), unless contraindicated or clinically significant effects are experienced". 4. References were reviewed and updated.	06/29/2023	07/13/2023
Policy was reviewed: 1. Updated Lines of Business Policy Applies to All lines of business (except Medicare). 2. Initial Approval Criteria and Continued Therapy Approval Criteria: Updated to remove prior dosing criteria. 3. Initial Approval Criteria, I.B: Updated to include approval criteria for indication, Pruritus with ALGS. 4. Continuation Approval Criteria, II.A: Updated title. 5. Continued Therapy Approval Criteria, II.A.1: updated to "Member is currently receiving…". 6. References were reviewed and updated.	08/14/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 4. Removed other reauthorization	08/28/2024	9/13/2024

requirements including positive response to therapy. 5. References were reviewed and updated.		