Pharmacy Drug Policy & Procedure

Policy Name:	Bylvay (odevixibat)	Policy#:	3176P

Purpose of the Policy

The purpose of this policy is to define coverage criteria for Bylvay (odevixibat).

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Bylvay (odevixibat) under the specialty pharmacy benefit if the following criteria are met.

Criteria

1. Coverage Criteria for Pruritus due to Familial Intrahepatic Cholestasis

1.1 Diagnosis of pruritus (itching) due to progressive familial intrahepatic cholestasis (PFIC)
- Diagnosis confirmed by genetic testing showing biallelic pathogenic mutations in the ATP8B1 (ie, PFIC1) or ABCB11 (ie, PFIC2) genes

1.2 Member has cholestasis, as indicated by one of the following:
- Total serum bile acid >3 × upper limit of normal (ULN) for age
- Conjugated bilirubin >2 mg/dL
- Fat soluble vitamin deficiency that is otherwise unexplainable
- Gamma Glutamyl Transferase (GGT) >3 × ULN for age
- Intractable pruritus explainable only by liver disease

1.3 Age 3 months or older

1.4 Prescribed by or in consultation with a hepatologist (liver doctor)

1.5 Documented concurrent use or previous trial and failure, intolerance or contraindication ursodiol and cholestyramine

1.6 Review of chart notes documenting diagnosis and confirming that the patient has met all of the above requirements for treatment with Bylvay by both a pharmacist and medical director

2. Coverage Criteria for Pruritus due to Alagille Syndrome

2.1 Diagnosis of moderate to severe pruritus due to Alagille syndrome (ALGS)
- Diagnosis of ALGS confirmed by genetic testing showing pathogenic variants in the JAG1 or NOTCH2 genes

2.2 Member has cholestasis, as indicated by one of the following:
- Total serum bile acid >3 × upper limit of normal (ULN) for age
- Conjugated bilirubin >2 mg/dL
- Fat soluble vitamin deficiency that is otherwise unexplainable
- Gamma Glutamyl Transferase (GGT) >3 × ULN for age
- Intractable pruritus explainable only by liver disease

2.3 Age 12 months or older

2.4 Prescribed by or in consultation with a hepatologist (liver doctor)

2.5 Documented trial and failure, contraindication or intolerance to TWO of the following:
- Ursodiol

- Rifampin
- Cholestyramine
- Sertraline
- Naltrexone (not for pediatric patients)

2.6 Review of chart notes documenting diagnosis and confirming that the patient has met all of the above requirements for treatment with Bylvay by both a pharmacist and medical director

3. Exclusion Criteria

3.1 Genetic testing indicates PFIC with ABCB11 variants encoding for non-function or absence of BSEP-3
3.2 Pregnancy
3.3 Chronic diarrhea requiring consistent fluid or nutritional intervention
3.4 History of liver transplant or biliary diversion surgery within the past 6 months
3.5 Evidence of decompensated cirrhosis
3.6 Concurrent use with Livmarli

4. Managed Dose Limit

4.1 Oral capsules:#450 capsules/30 days (400mcg) and #150 capsules/30 days (1200mcg)
4.2 Oral sprinkle capsules: #900 capsules/30 days (200mcg) and #300 capsules/30 days (600mcg)

5. Approval Period

5.1 Initial: 12 months
5.2 Reauthorization: 12 months with documented improvement on therapy

CPT Codes	
HCPCS Codes	

References

1. Bylvay (odevixibat) [prescribing information]. Boston, MA: Albireo Pharma Inc; June 2023.
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3. Baumann U, Sturm E, Lacaille F, et al. Effects of odevixibat on pruritus and bile acids in children with cholestatic liver disease: Phase 2 study. Clin Res Hepatol Gastroenterol. 2021;45(5):101751.
4. Kamath BM, Ye W, Goodrich NP, et al; Childhood Liver Disease Research Network (ChiLDReN). Outcomes of Childhood Cholestasis in Alagille Syndrome: Results of a Multicenter Observational Study. Hepatol Commun. 2020 Jan 22;4(3):387-398.
5. Jacquemin E. Progressive familial intrahepatic cholestasis. Clin Res Hepatol Gastroenterol. 2012;36 Suppl1:S26-S35.
6. Cies JJ, Giamalis JN. Treatment of cholestatic pruritis in children. Am J Health Syst Phar 2007; 64:1157.

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DISCLAIMER

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