STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ODEVIXIBAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ODEVIXIBAT	BYLVAY	47501		GPI-10 (5235006000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of pruritus associated with progressive familial intrahepatic cholestasis (PFIC) **AND** meet the following criterion?
   - The patient is 3 months of age or older

   If yes, **approve for all strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **200mcg pellets: #30 per day.**
   - **400mcg capsule: #15 per day.**
   - **600mcg pellets: #10 per day.**
   - **1200mcg capsule: #5 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of cholestatic pruritus associated with Alagille syndrome (ALGS) **AND** meet the following criterion?
   - The patient is 12 months of age or older

   If yes, **approve for all strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **200mcg pellets: #36 per day.**
   - **400mcg capsule: #18 per day.**
   - **600mcg pellets: #12 per day.**
   - **1200mcg capsule: #6 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ODEVIXIBAT (Bylvay)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Pruritus (itching) associated with progressive familial intrahepatic cholestasis (PFIC: an inherited liver condition)
      2. Cholestatic pruritus (itching caused by liver disease) associated with Alagille syndrome (ALGS: a type of genetic disorder)

   (Denial text continued on next page)

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ODEVIXIBAT

GUIDELINES FOR USE (CONTINUED)

B. **If you have pruritus associated with progressive familial intrahepatic cholestasis, approval also requires:**
   1. You are 3 months of age or older
C. **If you have cholestatic pruritus associated with Alagille syndrome, approval also requires:**
   1. You are 12 months of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bylvay.

REFERENCES

- Bylvay [Prescribing Information]. Boston, MA: Albireo Pharma, Inc.; June 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/23
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P&T Approval: 07/23