Criteria-Based Consultation Prescribing Program
CRITERIA FOR DRUG COVERAGE
Odevixibat (Bylvay)

Notes:

- Quantity Limits: Yes, 6mg per day for PFIC
- ^ Adequate trial is defined as 6 month treatment duration
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

Initiation (new start) criteria: Non-formulary **odevixibat (Bylvay)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Patient has a diagnosis of pruritis due to progressive familial intrahepatic cholestasis (PFIC: an inherited liver condition without type 2 specific ABCB11 variants) AND is at least 3 months old **OR** patient has a diagnosis of Alagille syndrome (ALGS: an inherited liver condition) AND is at least 12 months old
- Prescribed by Gastroenterology or Hepatology Provider
- Patient has failed an adequate trial^ of at least two other conventional treatments for the symptomatic relief of pruritis (cholestyramine or other bile acid sequestrant, naltrexone, rifampin, ursodeoxycholic acid) or patient has an allergy or intolerance* to at least two other conventional treatments as listed above.
- Patient does not have prior or active hepatic decompensation events (variceal hemorrhage, ascites, hepatic encephalopathy)

Criteria for *new members* entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary **odevixibat (Bylvay)** will be covered on the prescription drug benefit for 6 months when the following criteria are met:

- Patient has a diagnosis of pruritis due to progressive familial intrahepatic cholestasis (PFIC: an inherited liver condition)
- Prescribed by Gastroenterology or Hepatology Provider
- Patient does not have prior or active hepatic decompensation events (variceal hemorrhage, ascites, hepatic encephalopathy)

Continued use criteria for patients previously approved per the above criteria who are currently stable on the medication: Non-formulary **odevixibat (Bylvay)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by Gastroenterology or Hepatology Provider
- Patient does not have prior or active hepatic decompensation events (variceal hemorrhage, ascites, hepatic encephalopathy)

Odevixibat (Bylvay)

- Documentation of clinical improvement from baseline pruritis