Criteria-Based Consultation Prescribing Program
CRITERIA FOR DRUG COVERAGE
Elafibranor (Iqirvo)

Notes:

- Quantity Limits: Yes
- ^ Adequate trial is defined as an alkaline phosphatase (ALP) ≥ 1.67 times upper limit of normal after 6-12 months of treatment at UDCA doses of 13-15mg/kg/day
- * 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 **elafibranor (Iqirvo)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by hepatology provider
- Patient has a diagnosis of primary biliary cholangitis and is 18 years or older
- Patient has failed an adequate trial^ of ursodeoxycholic acid (UDCA) or patient has an allergy or intolerance* to UDCA
- Adherence to UDCA is confirmed
- Patient is taking optimal regimen for pruritis management, including anion-exchange resins (cholestyramine) or fibrates
- Patient does not have history of decompensated cirrhosis (Child-Pugh B or C)
- Patient is not pregnant or breastfeeding

Criteria for *new members* entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary **elafibranor (Iqirvo)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by hepatology provider
- Patient has a diagnosis of primary biliary cholangitis and is 18 years or older
- Patient has failed an adequate trial^ of UDCA or patient has an allergy or intolerance* to UDCA
- Adherence to UDCA is confirmed
- Patient is taking optimal regimen for pruritis management, including anion-exchange resins (cholestyramine) or fibrates
- Patient does not have history of decompensated cirrhosis (Child-Pugh B or C)
- Patient is not pregnant or breastfeeding

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

- Prescribed by hepatology provider
- Adequate response to elafibranor defined as a reduction in ALP to less than 1.67 times upper limit of normal and an ALP decrease of at least 15% since the start of treatment.
- Patient has completed liver function laboratory monitoring within the last 3 months (ALP, AST, ALT, total bilirubin).
- Adherence to treatment confirmed.