BlueCross BlueShield Federal Employee Program

IQIRVO
(elafibranor)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Iqirvo (elafibranor) and its main active metabolite GFT1007 are peroxisome proliferator-activated receptor (PPAR) agonists, both of which activate PPAR-alpha, PPAR-gamma, and PPAR-delta in vitro. However, the mechanism by which Iqirvo exerts its therapeutic effects in patients with primary biliary cholangitis (PBC) is not well understood. Pharmacological activity that is potentially relevant to therapeutic effects includes inhibition of bile acid synthesis through activation of PPAR-alpha and PPAR-delta. The signaling pathway for PPAR-delta was reported to include Fibroblast Growth Factor 21 (FGF21)-dependent downregulation of CYP7A1, the key enzyme for the synthesis of bile acids from cholesterol (1).

Regulatory Status

FDA-approved indication: Iqirvo is a peroxisome proliferator-activated receptor (PPAR) agonist indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA (1).

Limitations of Use: Use of Iqirvo is not recommended in patients who have or develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy) (1).

Iqirvo has been associated with myalgia, myopathy, and rhabdomyolysis. Patients should be assessed for muscle pain and myopathy prior to Iqirvo initiation. Patients with signs or symptoms of new onset or worsening of muscle pain or myopathy should consider periodic assessment (clinical exam, CPK measurement) (1).

Iqirvo use may result in fractures, drug-induced liver injury, and biliary obstruction. Consider risk of fractures and monitor bone health according to current standards of care. Baseline liver function tests should be obtained at treatment initiation with Iqirvo and monitored thereafter. Treatment should be interrupted if liver tests worsen, or if the patient develops signs and symptoms consistent with clinical hepatitis. Consider discontinuation if liver tests worsen after restarting Iqirvo. Avoid use of Iqirvo in patients with complete biliary obstruction. If biliary obstruction is suspected, interrupt Iqirvo and treat as clinically indicated (1).

BlueCross BlueShield Federal Employee Program

IQIRVO
(elafibranor)

Iqirvo may cause fetal harm when administered during pregnancy. Advise females of reproductive potential to use effective non-hormonal contraceptives or add a barrier method when using hormonal contraceptives during treatment with Iqirvo and for 3 weeks following the last dose of Igirvo (1).

The safety and effectiveness of Iqirvo in pediatric patients less than 18 years of age have not been established (1).

Summary

Iqirvo (elafibranor) is a PPAR agonist indicated for the treatment of PBC. Iqirvo is not recommended in patients who have or develop decompensated cirrhosis. Iqirvo has been associated with myalgia, myopathy, rhabdomyolysis, fractures, potential risk to a fetus, drug-induced liver injury, and biliary obstruction. The safety and effectiveness of Iqirvo in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Iqirvo while maintaining optimal therapeutic outcomes.

References

1. Iqirvo [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; June 2024.