Mass General Brigham
Health Plan

Iqirvo (elafibranor)
Effective 01/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Iqirvo (elafibranor) 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.

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

Coverage Guidelines
Authorization may be granted for members new to the plan within the last 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met:

1. Member has a diagnosis of primary biliary cholangitis (PBC) confirmed by at least two of the following:
    a. Biochemical evidence of cholestasis with elevation of alkaline phosphatase (ALP) level
    b. Presence of antimitochondrial antibodies (AMA) or PBC-specific antinuclear antibodies (ANA) (e.g., anti-gp210, anti-sp100)
    c. Histologic evidence of PBC on liver biopsy (e.g., non-suppurative inflammation and destruction of interlobular and septal bile ducts)
2. Member had an inadequate response for at least 12 months of treatment with UDCA (recommended dose is 13-15 mg/kg/day), or member had an intolerance to UDCA
3. Member does not have decompensated cirrhosis
4. Iqirvo is prescribed by or in consultation with a gastroenterologist or hepatologist
5. Iqirvo will not be used in combination with either of the following: obeticholic acid, seladelpar

Continuation of Therapy

Requests for reauthorization will be approved when the following criteria are met:

1. Member has demonstrated a positive response to therapy as indicated by at least one of the following:
    a. Alkaline phosphatase (ALP) less than 1.67 times the upper limit of normal (ULN)
    b. Total bilirubin less than or equal to the ULN
    c. ALP decrease greater than or equal to 15% from baseline
2. Member continues to not use Iqirvo in combination with either of the following: obeticholic acid, seladelpar

Limitations

1. Initial and reauthorization requests will be approved for 12 months.
2. The following quantity limits apply:

Drug Name	Quantity Limit
Iqirvo tablet	1 tablet per day

References

1. Bowlus CL, Kowdley KV, Levy C, et al. Efficacy of elafibranor in primary biliary cholangitis: Results from the variable double-blind period of ELATIVE®, a randomised, placebo-controlled phase III trial. Poster presented at: European Association for the Study of the Liver (EASL); June 5-8, 2024; Milan, Italy.
2. Brookhart MA, Coombs C, Breskin A, et al. Results of the HEROES study: treatment efficacy of obeticholic acid on hepatic real-world outcomes in patients with primary biliary cholangitis. PowerPoint presented at: AASLD The Liver Meeting. November 4-8, 2022, Washington, DC.
3. Corpechot C, Carrat F, Poujol-Robert A, et al. Noninvasive elastography-based assessment of liver fibrosis progression and prognosis in primary biliary cirrhosis. *Hepatology*. 2012;56(1):198-208. doi: 10.1002/hep.25599.
4. Day J, Patel P, Parkes J, Rosenberg W. Derivation and performance of standardized enhanced liver fibrosis (ELF) test thresholds for the detection and prognosis of liver fibrosis. *J Appl Lab Med*. 2019;3(5):815-826. doi: 10.1373/jalm.2018.027359.
5. Food and Drug Administration (FDA) news release. FDA approves Ocaliva for rare, chronic liver disease**.** May 31, 2016. Accessed June 27, 2024. https://www.fda.gov/news-events/press-announcements/fda-approves-ocaliva-rare-chronic-liver-disease
6. Iqirvo (elafibranor) [prescribing information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; June 2024.
7. Kowdley KV, Bowlus C, Levy C, et al. Application of the latest advances in evidence-based medicine in primary biliary cholangitis. Am J Gastroenterol. 2023;118(2):232-242.
8. Kowdley KV, Bowlus CL, Levy C, et al. Efficacy and safety of elafibranor in primary biliary cholangitis. *New Engl J Med*. 2024;390(9):794-805.
9. Lindor KD, Bowlus CL, Boyer J, Levy C, Mayo M. Primary biliary cholangitis: 2018 practice guidance from the American association for the study of liver diseases. *Hepatology*. 2019;69(1):394-419. doi: 10.1002/hep.30145.
10. Lindor KD, Bowlus CL, Boyer J, Levy C, Mayo M. Primary biliary cholangitis: 2021 practice guidance update from the American Association for the Study of Liver Diseases. *Hepatology*. 2022;75(4):1012-1013.

11. Murrillo Perez CF, Fisher H, Hiu S, et al. Greater transplant-free survival in patients receiving obeticholic acid for primary biliary cholangitis in a clinical trial setting compared to real-world external controls. *Gastroenterology*. 2022;163(6):1630-1642.e3. doi: 10.1053/j.gastro.2022.08.054.
12. Nevens F, Andreone P, Mazzella G, et al. A placebo-controlled trial of obeticholic acid in primary biliary cholangitis. *New Engl J Med*. 2016;375(7):631-643.
13. Trauner M, Nevens F, Shiffman ML, et al. Long-term efficacy and safety of obeticholic acid for patients with primary biliary cholangitis: 3-year results of an international open-label extension study. *Lancet Gastroenterol Hepatol.* 2019;4(6):445-453.

Review History

10/09/2024 – Reviewed at October P&T. Effective 01/01/2025.