Iqirvo® (elafibranor) and Livdelzi® (seladelpar)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Iqirvo and Livdelzi are 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.

This indication is approved under accelerated approval based on a reduction in alkaline phosphatase (ALP). Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Limitations of Use

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

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. For initial requests: Pretreatment serum alkaline phosphatase (ALP) level

2. For continuation of therapy: Current serum alkaline phosphatase (ALP) and/or current total bilirubin level

Exclusions

Coverage will not be provided for members who have or develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy).

Prescriber Specialties

The requested medication must be prescribed by or in consultation with one of the following:

1. Hepatologist
2. Gastroenterologist

Criteria for Initial Approval

Primary biliary cholangitis (PBC) (previously known as primary biliary cirrhosis)

Authorization of 12 months may be granted for treatment of PBC in adult patients when all of the following criteria are met:

1. Diagnosis of PBC is confirmed by at least two of the following criteria:
    A. Biochemical evidence of cholestasis with elevation of alkaline phosphatase (ALP) level for at least 6 months duration.
    B. Presence of antimitochondrial antibodies (AMA) (titer >1:40 by immunofluorescence or immunoenzymatic reactivity) 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. Patient has an elevated serum ALP level prior to initiation of therapy with the requested drug
3. Patient meets either of the following criteria:
    A. Patient has had an inadequate response to at least 12 months of prior therapy with ursodeoxycholic acid (UDCA)/ursodiol and the member will continue concomitant therapy with UDCA/ursodiol.
    B. Patient has an intolerance to UDCA/ursodiol.

Continuation of Therapy

Primary biliary cholangitis (PBC) (previously known as primary biliary cirrhosis)

Authorization of 12 months may be granted for members who have achieved or maintained a clinical benefit from the requested medication (e.g., at least a 15% reduction in ALP level, ALP level less than 1.67 times upper limit of normal [ULN], total bilirubin less than or equal to ULN).

Other

Iqirvo (elafibranor) and Livdelzi (seladelpar) are considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Iqirvo (elafibranor) 80 mg oral tablet	30 tablets per 30 days	80 mg orally once daily

Livdelzi (seladelpar) 10 mg oral capsule	30 capsules per 30 days	10 mg orally once daily

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

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

Livdelzi [package insert]. Foster City, CA: Gilead Sciences, Inc.; August 2024.

Lindor KD, Bowlus CL, Boyer J, et al. Primary biliary cholangitis: 2018 Practice guidance from the American Association for the study of liver diseases. Hepatology. 2019;69(1):394-419.

European Association for the Study of the Liver. EASL clinical practice guidelines: The diagnosis and management of patients with primary biliary cholangitis. J Hepatol. 2017;67(1):145-172.

POLICY HISTORY

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