AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Livdelzi	Page:	1 of 2
Effective Date:	11/29/2024	Last Review Date:	10/25/2024
Applies to:	☒Illinois ☒Florida Kids	☒New Jersey ☒Pennsylvania Kids	☒Maryland ☐Virginia

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Livdelzi under the patient's prescription drug benefit.

Description:

FDA-Approved Indication

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

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Livdelzi

Policy/Guideline:

Documentation

Submission of the following information is necessary for the prior authorization review:

A. Initial requests: Pretreatment serum alkaline phosphatase (ALP) level
B. Continuation of therapy: Current serum alkaline phosphatase (ALP) and/or current total bilirubin level

Prescriber Specialties

This medication must be prescribed by or in consultation with a hepatologist or gastroenterologist.

Exclusions

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

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 members when ALL the following criteria are met:

A. Diagnosis of PBC is confirmed by at least TWO of the following criteria:
   1. Biochemical evidence of cholestasis with elevation of alkaline phosphatase (ALP) level for at least 6 months duration.
   2. 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).
   3. Histologic evidence of PBC on liver biopsy (e.g., non-suppurative inflammation and destruction of interlobular and septal bile ducts).

B. Member has an elevated serum ALP level prior to initiation of therapy with the requested drug.

C. Member meets EITHER of the following criteria:
   1. Member 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.
   2. Member has an intolerance to UDCA/ursodiol.

Criteria for Continuation of Therapy

Authorization of 12 months may be granted for members who have achieved or maintained a clinical benefit from Livdelzi therapy as evidenced by ANY of the following:

A. At least a 15% reduction in serum ALP level
B. Serum ALP level less than 1.67 times upper limit of normal (ULN)
C. Total bilirubin less than or equal to ULN

Approval Duration and Quantity Restrictions:

Initial and Renewal Approval: 12 months

Quantity Level Limit: 30 capsules per 30 days

References:

1. Livdelzi [package insert]. Foster City, CA: Gilead Sciences, Inc.; August 2024.
2. 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.
3. 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.