Original Effective Date: 12/14/2024
Current Effective Date: 04/11/2025
Last P&T Approval/Version: 01/29/2025
Next Review Due By: 01/2026
Policy Number: C28776-A

Livdelzi (seladelpar lysine)

PRODUCTS AFFECTED

Livdelzi (seladelpar lysine)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Primary biliary cholangitis (PBC)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. PRIMARY BILIARY CHOLANGITIS:
   1. Documented diagnosis of primary biliary cholangitis (PBC)
      AND
   2. Documentation of TWO of the following that support the diagnosis [DOCUMENTATION REQUIRED]:

i. Biochemical evidence of cholestasis based on alkaline phosphatase (ALP) elevation
ii. Presence of antimitochondrial antibody (AMA) or other PBC- specific autoantibodies (including sp100 or gp210, if AMA is negative)
iii. Histologic evidence of nonsuppurative destructive cholangitis and destruction of interlobular bile ducts

AND

3. Documentation of the member's baseline (prior to treatment) alkaline phosphatase (ALP) level [DOCUMENTATION REQUIRED]
AND
4. Documentation member has been receiving ursodiol therapy (e.g., ursodiol generics, Urso250®, UrsoForte®, Actigall®) for ≥ 1 year at doses of 13-15 mg/kg/day and has had an inadequate response (alkaline phosphatase level > 1.67 times the upper limit of normal); OR According to the prescribing physician the member is unable to tolerate ursodiol therapy
AND
5. Member is not on concurrent treatment or will not be used in combination with Ocaliva or Iqirvo as verified by prescriber attestation, member medication fill history, or submitted documentation
AND
6. Prescriber attests (or the clinical reviewer has found that) the member does not have decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy)
AND
7. Prescriber attests they will monitor the member for hepatic adverse events
AND
8. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

CONTINUATION OF THERAPY:

A. PRIMARY BILIARY CHOLANGITIS:
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
AND
2. Documentation of positive response to therapy as indicated by alkaline phosphatase (ALP) decrease of at least 15% from pretreatment AND is less than 1.67-times the upper limit of normal (ULN) [DOCUMENTATION REQUIRED]
AND
3. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
AND
4. Prescriber attests that member does not have cirrhosis OR for a member that has cirrhosis, that the member has compensated cirrhosis and has not had a decompensation event. NOTE: Livdelzi is not recommended in members who have or who develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy)
AND
5. Documentation the member continues to receive ursodiol therapy OR According to the prescribing physician the member is unable to tolerate ursodiol therapy

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician. [If

prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests.]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
10 mg orally once daily

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Peroxisome Proliferator-Activated Receptor Agonists

FDA-APPROVED USES:
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 of 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).

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Livdelzi is indicated for treating PBC alongside ursodeoxycholic acid (UDCA) in adults who do not respond adequately to UDCA, or as a standalone treatment for those who cannot tolerate UDCA. This indication has received accelerated approval due to a reduction in alkaline phosphatase (ALP) levels. However, improvements in survival or the prevention of liver decompensation events have not been established. Ongoing approval for this indication may depend on confirming and detailing clinical benefits in further trials.

Livdelzi is a peroxisome proliferator-activated receptor (PPAR)-delta agonist. However, the precise mechanism through which seladelpar produces its therapeutic effects in patients with PBC remains unclear.

Its pharmacological activity, which may be relevant to these effects, includes the inhibition of bile acid synthesis via PPAR-delta activation, a nuclear receptor found in various tissues, including the liver. Research indicates that seladelpar's activation of PPAR-delta leads to a reduction in bile acid synthesis by downregulating CYP7A1, an essential enzyme in bile acid synthesis from cholesterol, through a Fibroblast Growth Factor 21 (FGF21)-dependent mechanism.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Livdelzi (seladelpar lysine) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Livdelzi (seladelpar) include: No labeled contraindications. Avoid use in patients with complete biliary obstruction.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Livdelzi CAPS 10MG

REFERENCES

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7. Intercept announces new clinical trial and real-world outcomes data for Ocaliva in PBC. News release.

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Contraindications/Exclusions/Discontinuation References	Q1 2025
NEW CRITERIA CREATION	Q4 2024