Clinical Policy: Seladelpar (Livdelzi)

Reference Number: CP.PHAR.698
Effective Date: 12.01.24
Last Review Date: 11.26
Line of Business: Commercial, HIM/ICHRA, Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Seladelpar (Livdelzi®) is a peroxisome proliferator-activated receptor (PPAR)-delta agonist.

FDA Approved Indication(s)

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.*

Limitation(s) of use: Use of Livdelzi is not recommended in patients who have or develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy).

**This indication is approved under accelerated approval based on 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).*

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Livdelzi is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Primary Biliary Cholangitis (must meet all)**:**

1. Diagnosis of PBC;
2. Prescribed by or in consultation with a hepatologist or gastroenterologist;
3. Age ≥ 18 years;
4. Failure (as evidenced by sustained elevation in ALP ≥ 1.67 times the upper limit of normal) of ≥ 12 month trial of UDCA (ursodiol) at a dose of ≥ 13 mg/kg/day, unless contraindicated or clinically significant adverse effects are experienced;
5. Prescribed in combination with UDCA (ursodiol), unless contraindicated or clinically significant adverse effects are experienced;
6. Member does not have decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy);
7. Livdelzi is not prescribed concurrently with Iqirvo®;
8. Dose does not exceed 10 mg (1 capsule) per day.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Primary Biliary Cholangitis (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Member is responding positively to therapy as evidenced by one of the following (a or b):
   a. Initial reauthorization: reduction in ALP level from pretreatment level;
   b. Subsequent reauthorization: continued reduction or maintenance of initial reduction in ALP level;
3. Livdelzi is not prescribed concurrently with Iqirvo;
4. If request is for a dose increase, new dose does not exceed 10 mg (1 capsule) per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the

relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AASLD: American Association for the Study of Liver Diseases
ALP: alkaline phosphatase
FDA: Food and Drug Administration
PBC: primary biliary cholangitis
PPAR: peroxisome proliferator-activated receptor
TB: total bilirubin
UDCA: ursodeoxycholic acid

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
ursodiol (Urso Forte®)	13-15 mg/kg/day PO in 2-4 divided doses	15 mg/kg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: General Information

- According to the AASLD Primary Biliary Cirrhosis 2018 practice guidelines, UDCA dosed at 13-15 mg/kg/day orally is recommended for all patients with PBC who have abnormal liver enzyme values regardless of histological stage. Improvement in liver tests will be seen within a matter of a few weeks and 90% of the improvement usually occurs within 6-9 months. The eligibility criteria in the Livdelzi efficacy trial required enrolled patients to have a minimum 12 month history of taking UDCA.
- In the Livdelzi clinical trial, biochemical response was defined as achieving ALP less than 1.67-times ULN, an ALP decrease of greater than or equal to 15% from baseline, and total bilirubin (TB) less than or equal to ULN. The ULN for ALP was defined as 116 U/L. The ULN for TB was defined as 1.1 mg/dL.

- At month 12, improvement in ALP was the main contributor to the biochemical response rate results.

- A diagnosis of PBC can be established when two of the following three criteria are met:
  - ALP is elevated above the upper limit of normal as defined by normal laboratory references values;
  - Positive anti-mitochondrial antibodies (AMA) or other PBC-specific auto-antibodies, including sp100 or gp210, if AMA is negative;
  - Histologic evidence of PBC from a liver biopsy.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
PBC	10 mg PO QD	10 mg/day

VI. Product Availability

Capsule: 10 mg

VII. References

1. Livdelzi Prescribing Information. Foster City, CA: Gilead Sciences, Inc; January 2026. Available at: https://www.gilead.com/-/media/files/pdfs/medicines/pbc/livdelzi/livdelzi_pi.pdf. Accessed July 10, 2026.
2. Hirschfield GM, Bowlus CL, Kremer AE et cal. A phase 3 trial of seladelpar in primary biliary cholangitis. NEJM 2024;390(9):783-794.
3. Lindor KD, Bowlus CL, Boyer J, et al. Primary biliary cholangitis: 2018 practice guidance from the American Association for the Study of Liver Diseases (AASLD). Hepatology. 2018; 0(0): 1-26. Available at: https://journals.lww.com/hep/Fulltext/2019/01000/Primary_Biliary_Cholangitis__2018_Practice.32.aspx. Accessed August 23, 2026.
4. Lindor KD, Bowlus CL, Boyer J, et al. Primary biliary cholangitis: 2021 practice guidance update from the American Association for the study of liver diseases. Hepatology. 2022 April;75(4):1012-1013.
5. European Association for the Study of the Liver (EASL). EASL clinical practice guidelines: the diagnosis and management of patients with primary biliary cholangitis. J Hepatology. 2017;67:145-72.
6. Levy C, Manns M and Hirschfield G. New treatment paradigms in primary biliary cholangitis. Clinical Gastroenterology and Hepatology 2023;21:2076-2087.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08.27.24	11.24
4Q 2025 annual review: no significant changes; references reviewed and updated.	07.15.25	11.25
4Q 2026 annual review: added ICHRA line of business; added requirement that Livdelzi is not prescribed concurrently with Iqirvo to initial and continued therapy to prevent duplicate therapy; added requirement that member does not have decompensated cirrhosis	07.10.26	11.26

Reviews, Revisions, and Approvals	Date	P&T Approval Date
(e.g., ascites, variceal bleeding, hepatic encephalopathy) per prescribing information; references reviewed and updated.		

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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