

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3189-1
Program	Step Therapy
Medication	Livdelzi® (seladelpar)
P&T Approval Date	12/2024
Effective Date	3/1/2025

1. Background:

Step therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try and fail ursodeoxycholic acid (e.g., Urso, ursodiol) before providing coverage for Livdelzi® (seladelpar).

2. Coverage Criteria^a:**A. Primary biliary cholangitis**

1. **Livdelzi** will be approved based on **all** of the following criteria:

a Diagnosis of primary biliary cholangitis

-AND-

b. **One** of the following[^]:

(1) Patient has not achieved an adequate response to an appropriate dosage of ursodeoxycholic acid (e.g., Urso, ursodiol) after at least 12 consecutive months of therapy

-OR-

(2) History of contraindication or intolerance to ursodeoxycholic acid (e.g., Urso, ursodiol)

-OR-

(3) **Both** of the following:

(a) As continuation of therapy

-AND-

(b) Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Gilead sponsored Gilead Support Path Program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Livdelzi

Authorization will be issued for 12 months.

B. Other Diagnoses

1. **Livdelzi** will be approved

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

[^]Tried/failed alternative(s) are supported by FDA labeling.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class. Supply limits and/or Notification may be in place.

4. References:

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

Program	Step Therapy – Livdelzi (seladelpar)
Change Control	
Date	Change
12/2024	New program.