Louisiana Medicaid
Resmetirom (Rezdiffra®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for resmetirom (Rezdiffra®).

Additional Point-of-Sale edits may apply.

By submitting the authorization request, the prescriber attests to the conditions available HERE.

This indication is approved under accelerated approval based on improvement of NASH and fibrosis. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Approval Criteria for Initiation of Therapy

- The recipient is 18 years of age or older on the date of the request; **AND**
- The recipient has **ALL** of the following confirmed by liver biopsy obtained within the previous 6 months [Date and results of liver biopsy must be **stated on the request**]:
    - Diagnosis of nonalcoholic steatohepatitis (NASH); **AND**
    - Fibrosis stage 2 or 3; **AND**
    - NAFLD Activity Score (NAS) ≥ 4; **AND**
- The prescriber **states on the request** that the recipient does not have evidence of decompensated cirrhosis; **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a gastroenterologist or hepatologist; **AND**
- The prescriber **states on the request** that resmetirom treatment will be used as adjunct treatment to standard of care therapy, which includes, but is not limited to:
    - Optimized pharmacotherapy for established metabolic and cardiovascular conditions; **AND**
    - Behavioral modification, including a reduced calorie diet and increased physical activity.

Approval Criteria for Continuation of Therapy

- The recipient has received < 1 year of therapy with resmetirom, the prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy; **OR**
- If the recipient has received ≥ 1 year and < 2 years of therapy with resmetirom, the prescriber **states on the request** that there is evidence of a positive response to treatment as indicated by **ONE** of the following:
    - Resolution of NASH **AND** no worsening of fibrosis stage; **OR**
    - No worsening of NASH **AND** an improvement of fibrosis by at least 1 stage; **OR**
- If the recipient has received >2 years of therapy with resmetirom, the prescriber **states on the request** that there is evidence of a positive response to treatment as indicated by **ONE** of the following:
    - Resolution of NASH **AND** no worsening of fibrosis stage; **OR**

    - No worsening of NASH **AND** no worsening of fibrosis stage; **AND**
- The prescriber **states on the request** that the recipient has not advanced to fibrosis stage 4.

Duration of approval for initiation and continuation of therapy: 12 months

References

ClinicalTrials.gov. A Phase 3 Study to Evaluate the Efficacy and Safety of MGL-3196 (Resmetirom) in Patients With NASH and Fibrosis (MAESTRO-NASH). https://clinicaltrials.gov/study/NCT03900429

Kanwal F, Shubrook JH, Adams LA, et al. Clinical care pathway for the risk stratification and management of patients with nonalcoholic fatty liver disease. Gastroenterol. 2021;161:1657- 1669.

Rezdiffra (resmetirom) [package insert]. West Conshohocken, PA: Madrigal Pharmaceuticals, Inc; March 2024. https://www.madrigalpharma.com/wp-content/uploads/2024/03/Prescribing-Information.pdf

Revision / Date	Implementation Date
Policy Created / May 2024	October 2024