STATE OF WEST VIRGINIA
DEPARTMENT OF HUMAN SERVICES
BUREAU FOR MEDICAL SERVICES

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**Office of Pharmacy Services**
**Prior Authorization Criteria**
**Rezdiffra® (resmetirom)**
***Effective 9/24/2025***

**Prior Authorization Request Form**

**REZDIFFRA** is a thyroid hormone receptor-beta (THR-beta) agonist indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).

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.

**Limitations of Use: Avoid use of REZDIFFRA in patients with decompensated cirrhosis.**

*In 2023, global liver disease societies and patient groups agreed to update the terminology for fatty liver diseases. Nonalcoholic steatohepatitis (NASH) was renamed metabolic dysfunction - associated steatohepatitis (MASH). For the purposes of these criteria, NASH and MASH are considered interchangeable terms, though individual product labels may still use older terminology.

**CRITERIA FOR APPROVAL:**

1. Patient has a diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis); **AND**

2. Diagnosis of NASH is confirmed by **ONE** of the following:

   a) Liver biopsy within the past one year **and** the results show non-alcoholic fatty liver disease activity score of ≥ 4 with a score of > 1 in **ALL** the following: Steatosis, Ballooning, and Lobular inflammation; **OR**

   b) Liver stiffness measurement by vibration-controlled transient elastography (for example FibroScan) or magnetic resonance elastography (MRE); **AND**

3. The patient has stage 2 or stage 3 Fibrosis; **AND**

4. Patient is within the age range as recommended by the Food and Drug Administration (FDA) label; **AND**

5. Must be prescribed by, or in consultation with, an M.D./D.O. or a specialty trained prescriber with a clinical specialty certification/degree in gastroenterology or hepatology; **AND**

6. The patient has completed a documented trial of a GLP-1 receptor agonist (indicated for MASH) for at least six months, unless contraindicated or not tolerated. Documentation must show **ONE** of the following:

a) Inadequate response: <5% reduction in baseline body weight after ≥ six months of therapy; or
b) No improvement in liver stiffness or fibrosis markers on imaging/biopsy; or
c) No meaningful improvement in liver biochemistry (ALT or AST) or
d) Intolerance or contraindication to GLP-1 therapy (history of pancreatitis, medullary thyroid carcinoma, persistent gastrointestinal intolerance); **AND**

7. The medication will be used in combination with appropriate diet and exercise therapy (Please describe and submit documentation of diet, exercise and weight loss counseling/treatment provided within the past 12 months); **AND**

8. The patient has three metabolic risk factors from the following: central obesity, hypertriglyceridemia, reduced high-density lipoprotein cholesterol, hypertension, elevated fasting plasma glucose indicative of diabetes or pre-diabetes; **AND**

9. The patient is compliant on stable dosages of medications for diabetes, dyslipidemia, and hypertension (where applicable).

**Initial approvals will be for 90 days. Further approvals may be granted for one year after all the continuation of therapy criteria has been met.**

**CONTINUATION OF THERAPY CRITERIA:**

1) Patient continues to meet all initial approval criteria; **AND**
2) Demonstrate continued documented compliance; **AND**
3) The patient has not progressed to stage F4 (cirrhosis); **AND**
4) Documentation of positive clinical response to Rezdiffra therapy (such as resolution of steatohepatitis and no worsening of liver fibrosis or at least one stage improvement in liver fibrosis and no worsening of steatohepatitis).