New Hampshire Medicaid Fee-for-Service Program Rezdiffra® (resmetirom) Criteria

Approval Date: June 10, 2024

Medications

Brand Names	Generic Names	Indication
Rezdiffra®	**resmetirom**	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)

Criteria for Approval

1. Patient is 18 years of age or older; **AND**
2. Prescribed by or in consultation with a gastroenterologist or hepatologist; **AND**
3. The patient has a diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH); **AND**
4. The patient has moderate to advanced liver fibrosis as determined by **one** of the following:
   - Liver biopsy within the past 2 years confirming steatosis **AND**
     - Nonalcoholic fatty liver disease (NAFLD) activity score (NAS) 4 or more; **AND**
     - Score of 1 or more in each NAS component (e.g., steatosis [scored 0 to 3], ballooning degeneration [scored 0 to 2], lobular inflammation [scored 0 to 3]); **AND**
     - Fibrosis stage 1, 2, or 3; **OR**
   - Vibration-controlled transient elastography (e.g., Fibroscan) with 8.5 kilopascals (kPA) or more **and** controlled attenuation parameter (CAP) score 280 decibels per meter (dB/m) or more; **OR**
   - Magnetic resonance elastography (MRE) 2 or more but less than 4; **OR**
   - **One** of the following historical biochemical tests for fibrosis:
     - PRO-C3 of more than 14 nanograms per milliliter (ng/mL); **OR**
     - Enhanced liver fibrosis (ELF) score of 9 or more; **AND**
5. Patient has a magnetic resonance imaging proton density fat fraction (MRI-PDFF) 8% or more liver fat; **AND**
6. Patient has **one** of the following:
   - Currently treated with a statin (e.g., atorvastatin, rosuvastatin, simvastatin) **and** will continue the statin; **OR**
   - Intolerance, hypersensitivity, or contraindication to **all** statins; **AND**
7. Patient has implemented lifestyle modifications (e.g., diet, exercise); **AND**
8. Patient does **not** have any of the following:

- History of significant alcohol consumption for more than 3 consecutive months within the previous 12 months
- Hepatocellular carcinoma (HCC)
- Any other liver disease (e.g., Wilson's disease, hepatitis)
- Model for end-stage liver disease (MELD) score of12 or more unless due to therapeutic anticoagulation
- History of bariatric surgery within the past year; **AND**

9. Patient is **not** taking a strong cytochrome P450 (CYP) 2C8 inhibitor (e.g., gemfibrozil); **AND**
10. Patient is **not** taking an organic anion-transporting polypeptides (OATP) 1B1 or OATP1B3 inhibitor (e.g., cyclosporine).

Initial approval period: 12 months

Criteria for Renewal

1. Patient must continue to meet the above criteria; **AND**
2. Patient must have disease improvement as evidenced by NASH resolution or improvement in liver fibrosis; **AND**
3. Patient has not experienced any treatment-restricting adverse effects (e.g., hepatotoxicity, gallbladder-related adverse reactions [e.g., cholelithiasis, acute cholecystitis, obstructive pancreatitis], statin-related adverse reactions [e.g., elevation of liver tests, myopathy, rhabdomyolysis] when given concurrently with a statin).

Renewal period: 12 months

Criteria for Denial

1. Failure to meet approval criteria.

References

Available upon request.

Revision History

Reviewed by	Reason for Review	Date Approved
DUR Board	New	05/07/2024
Commissioner designee	Approval	06/10/2024