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Rezdiffra- ARBCBS Custom Criteria

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Rezdiffra	resmetirom

Indications

FDA-approved Indications

Rezdiffra is 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.

Coverage Criteria

Noncirrhotic Nonalcoholic Steatohepatitis (NASH)

Authorization of 12 months may be granted when the requested drug is being prescribed for the treatment of an adult patient with noncirrhotic nonalcoholic steatohepatitis (NASH) [i.e., metabolic dysfunction-associated steatohepatitis (MASH)] with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) when ALL of the following criteria are met:

1. The requested drug will be used in conjunction with lifestyle interventions such as diet and exercise.
2. The patient has tried and failed to achieve clinical goals with lifestyle interventions (diet and exercise) for 6 months [ACTION REQUIRED: Documentation of formal diet and exercise plan required].
3. The requested drug is being prescribed by, or in consultation with, a gastroenterologist or hepatologist.
4. The patient’s moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) at baseline has been confirmed by ONE of the following: non-invasive liver disease assessment (e.g., ultrasound-based elastography, magnetic resonance elastography [MRE]) OR historical liver biopsy. [ACTION REQUIRED: Documentation is required for approval.] (Table 1)
5. There is no evidence of cirrhosis

Continuation of Therapy

Noncirrhotic Nonalcoholic Steatohepatitis (NASH)

Authorization of 12 months may be granted when the requested drug is being prescribed for the treatment of an adult patient with noncirrhotic nonalcoholic steatohepatitis (NASH) [i.e., metabolic dysfunction-associated steatohepatitis (MASH)] with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) when ALL of the following criteria are met:

1. The requested drug will be used in conjunction with diet and exercise.
2. The patient has achieved or maintained a positive clinical response to the requested drug (e.g., improvement in liver function such as reduction in alanine aminotransferase [ALT], improvement in Enhanced Liver Fibrosis (ELF) score, improvement in liver stiffness measurement [LSM] by ultrasound-based elastography, magnetic resonance elastography [MRE]). [ACTION REQUIRED: Documentation is required for approval.]
3. The patient has not progressed to cirrhosis

Table 1. Noninvasive test results suggestive of F2–F3 fibrosis

Noninvasive test	Result suggestive of F2–F3 fibrosis
FibroScan (VCTE)	8–15 kPa
ELF score	9.2-10.5
MRE (magnetic resonance elastography)	3.1–4.4 kPa

References

1. Rezdiffra [package insert]. West Conshohocken, PA: Madrigal Pharmaceuticals, Inc.; March 2024.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com. Accessed March 12, 2025.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 03/12/2025).
4. Chen VL, Morgan TR, Rotman Y, et al. Resmetirom therapy for metabolic dysfunction-associated steatotic liver disease: October 2024 updates to AASLD Practice Guidance. Hepatology. 2025;81(1):312-320.
5. Rinella ME, Neuschwander-Tetri BA, Siddiqui MS, et al. AASLD Practice Guidance on the clinical assessment and management of nonalcoholic fatty liver disease. Hepatology 2023;77(5): 1797-1835.