

Reference number(s)
7154-A

This document applies to the following:

Formulary	Applies
Advanced Control (ACF)	<input checked="" type="checkbox"/>
Advanced Control Formulary Chart (ACFC)	<input checked="" type="checkbox"/>
Advanced Control – Choice (ACCF)	<input checked="" type="checkbox"/>
Basic Control (BC)	<input type="checkbox"/>
Basic Control Chart (BCC)	<input type="checkbox"/>
Standard Control (SF)	<input checked="" type="checkbox"/>
Standard Control Formulary Chart (SFC)	<input checked="" type="checkbox"/>
Standard Control – Choice (SCCF)	<input checked="" type="checkbox"/>
Value (VF)	<input checked="" type="checkbox"/>
Value Formulary Chart (VFC)	<input checked="" type="checkbox"/>

Formulary	Applies
Managed Medicaid Template (MMT)	<input type="checkbox"/>
Marketplace (MF)	<input type="checkbox"/>
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	<input type="checkbox"/>
Aetna Individual Lives (IVL)	<input type="checkbox"/>
Aetna Fully Insured Advanced Control Formulary (Aetna FI ACF)	<input checked="" type="checkbox"/>
Aetna Fully Insured Advanced Control Formulary Chart (Aetna FI ACFC)	<input checked="" type="checkbox"/>
Aetna Fully Insured Standard Opt-Out (Aetna FI SOO)	<input type="checkbox"/>

Exception Criteria Rezdiffra

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).

Rezdiffra Exception (ACCF, ACF, ACFC, Aetna FI ACF, Aetna FI ACFC, SCCF, SF, SFC, VF, VFC) 7154-A P09-2025.docx © 2025 CVS Caremark. All rights reserved.

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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 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:

- The patient CANNOT be treated with a formulary alternative (Available Formulary Alternative: Wegovy)
- The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Wegovy. [ACTION REQUIRED: Documentation is required for approval.]
- The requested drug will be used in conjunction with diet and exercise.
- The requested drug is being prescribed by, or in consultation with, a gastroenterologist or hepatologist.
- 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.]

Continuation of Therapy

Noncirrhotic Nonalcoholic Steatohepatitis (NASH)

Authorization 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:

- The patient CANNOT be treated with a formulary alternative (Available Formulary Alternative: Wegovy)

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- The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to Wegovy. [ACTION REQUIRED: Documentation is required for approval.]
- The requested drug will be used in conjunction with diet and exercise.
- 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.]

Duration of Approval (DOA)

- 7154-A: DOA: 12 months

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 September 03, 2025.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 09/03/2025).
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.