AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Rezdiffra (resmetirom)	Page:	1 of 2
Effective Date:	7/1/2024	Last Review Date:	5/1/2024

Applies to:	☒Illinois	☐New Jersey	☒Virginia
	☒Maryland	☒Florida Kids	☒Pennsylvania Kids

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Rezdiffra under the patient's prescription drug benefit.

Description:

FDA-Approved Indication

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.

Applicable Drug List:

Rezdiffra

Policy/Guideline:

Criteria for Initial Approval:

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for an adult patient with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis)

AND

- The drug will be used in conjunction with diet and exercise

AND

  - The request is NOT for continuation of therapy

AND

    - The requested drug is being prescribed by, or in consultation with, a gastroenterologist or hepatologist

AND

    - The patient has stage F2 to F3 fibrosis at baseline confirmed by liver biopsy or magnetic resonance elastography (MRE). [ACTION REQUIRED: Documentation is required for approval.]

OR

- The request is for continuation of therapy
  AND
  - 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], reduction of liver fat content by imaging such as magnetic resonance imaging-protein density fat fraction [MRI-PDFF] or FibroScan controlled attenuation parameter [CAP])

Approval Duration and Quantity Restrictions:

Initial Approval: 12 months

Renewal Approval: 12 months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

References:

1. Rezdiffra [package insert]. West Conshohocken, PA: Madrigal Pharmaceuticals; March 2024.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed March 15, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 03/15/2023).
4. 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.