Effective Date:08/01/2024
Reviewed: 06/2024, 9/2025, 11/2025 Scope: Medicaid

Rezdiffra (resmetirom)

POLICY

I. INITIAL CRITERIA FOR APPROVAL

An authorization of 12 months may be granted when all the following criteria are met:

A. Member is 18 years or older; AND
B. Medication is prescribed by, or in consultation with a gastroenterologist or hepatologist; AND
C. Documentation that Rezdiffra is being prescribed for the treatment of non-cirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis); AND
D. The member's moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) at baseline has been confirmed by ONE of the following within the past 6 months:
    a. non-invasive liver disease assessment (e.g., ultrasound-based elastography, magnetic resonance elastography [MRE]); OR
    b. historical liver biopsy; AND
E. Documentation from the prescriber showing the member has THREE or more of the following metabolic risk factors that are managed according to standard of care.
    a. Central obesity
    b. Hypertriglyceridemia
    c. Reduced high-density lipoprotein cholesterol
    d. Hypertension
    e. Elevated fasting plasma glucose indicative of diabetes or pre-diabetes; AND
F. Documentation from the prescriber stating the member meets ONE of the following:
    a. Female member: Alcohol consumption is < 20 grams/day; OR
    Note: One standard drink (or one alcoholic drink equivalent) contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits.
    b. Male member: Alcohol consumption < 30 grams/day; AND
    Note: One standard drink (or one alcoholic drink equivalent) contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits.
G. The medication will be used in combination with a reduced calorie diet and increased physical activity; AND
H. If the member is GLP-1 naïve they must have documentation of an inadequate treatment response or intolerance, or contraindication from a 6-month trial of Wegovy (semaglutide) for MASH/NASH OR If the member is currently on a GLP-1 (e.g., Ozempic (semaglutide), Rybelsus (semaglutide), Trulicity (dulaglutide), etc.) the member must remain on therapy for 6 months of a FDA approved maintenance dose before starting Rezdiffra and updated labs/imaging submitted after the 6-month treatment period with a GLP-1 or Wegovy.

II. CONTINUATION OF THERAPY

An authorization of 12 months may be granted when all the following criteria are met:
A. A member who has received < 1 year of therapy or who is restarting therapy should be considered under Initial Therapy.

B. Member meets ONE of the following:
   a. Member has completed ≥ 1 year and < 2 years of therapy with Rezdiffra (note: this applies to a member starting their second year of therapy with Rezdiffra) and member has derived benefit from treatment Rezdiffra as demonstrated by at least ONE of the following, according to the prescriber:
      i. MASH/NASH resolution AND no worsening of fibrosis; OR
      ii. No worsening of MASH/NASH AND improvement in fibrosis by ≥ 1 stage; OR
   b. Member has completed ≥ 2 years of therapy with Rezdiffra (note: this applies to a member starting their third year (or more) of therapy with Rezdiffra (i.e., the member has already completed at least 2 years of therapy with Rezdiffra) AND according to the prescriber, the member has not had worsening of fibrosis or MASH/NASH; AND
C. Member has not progressed to stage F4 (cirrhosis); AND
D. Documentation that the member 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]); AND
E. Documentation from the prescriber stating the metabolic risk factors are managed according to standard of care; AND
F. Documentation from the prescriber, member meets ONE of the following:
   a. Female member: Alcohol consumption is < 20 grams/day; OR
   Note: One standard drink (or one alcoholic drink equivalent) contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits
   b. Male member: Alcohol consumption < 30 grams/day; AND
   Note: One standard drink (or one alcoholic drink equivalent) contains roughly 14 grams of pure alcohol, which is found in 12 ounces of regular beer, 5 ounces of wine, or 1.5 ounces of distilled spirits.
G. The medication will be used in combination with a reduced calorie diet and increased physical activity; AND
H. The medication is prescribed by or in consultation with a gastroenterologist, or hepatologist.

III. QUANTITY LIMIT

Rezdiffra 60mg, 80mg, & 100mg: 1 tablet per day

IV. REFERENCES

1. Rezdiffra [package insert]. West Conshohocken, PA: Madrigal Pharmaceuticals; February 2025.
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.