Effective Date:08/01/2024
Reviewed: 06/2024 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. Patient is 18 years or older; AND
B. Medication is prescribed by, or in consultation with a gastroenterologist or hepatologist; AND
C. The diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH)/ metabolic dysfunction–associated steatohepatitis (MASH), is confirmed by one of the following:
    a. Patient has had a liver biopsy AND meets BOTH of the following:
        i. Liver biopsy has been performed within the 6 months preceding treatment with Rezdiffra; AND
        ii. Liver biopsy shows non-alcoholic fatty liver disease activity score of ≥ 4 with a score of > 1 in ALL of the following:
            1. Steatosis; AND
            2. Ballooning; AND
            3. Lobular inflammation; OR
    b. Patient has had ONE of the following imaging exams performed within the 3 months preceding treatment with Rezdiffra:
        i. Elastography (Note: Examples of elastography include, but are not limited to vibration-controlled transient elastography (e.g., FibroScan), transient elastography, magnetic resonance elastography, acoustic radiation force impulse imaging, shear wave elastography); OR
        ii. Computed tomography; OR
        iii. Magnetic resonance imaging; OR
D. Patient meets ONE of the following prior to treatment with Rezdiffra.
    a. Patient has stage F2 fibrosis, OR
    b. Patient has stage F3 fibrosis; AND
E. Documentation from the prescriber, showing the patient 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 patient meets ONE of the following:
    a. Female patient: 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 patient: 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 an appropriate diet and exercise program; AND
H. If the patient has initiated on a GLP-1(e.g., Ozempic (semaglutide), Rybelsus (semaglutide), Trulicity (dulaglutide), etc.) the patient must remain on therapy for 6 months before starting Rezdiffra and updated labs/imaging submitted after the 6-month treatment period with a GLP-1.

II. CONTINUATION OF THERAPY

An authorization of 12 months may be granted when all the following criteria are met:
A. A patient who has received < 1 year of therapy or who is restarting therapy should be considered under Initial Therapy.
B. Patient meets ONE of the following:
    a. Patient has completed ≥ 1 year and < 2 years of therapy with Rezdiffra (note: this applies to a patient starting their second year of therapy with Rezdiffra) and patient 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. Patient has completed ≥ 2 years of therapy with Rezdiffra (note: this applies to a patient starting their third year (or more) of therapy with Rezdiffra (i.e., the patient has already completed at least 2 years of therapy with Rezdiffra) AND according to the prescriber, the patient has not had worsening of fibrosis or MASH/NASH; AND
C. Patient has not progressed to stage F4 (cirrhosis); AND
D. Documentation that the patient 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]); AND
E. Documentation from the prescriber stating the metabolic risk factors are managed according to standard of care; AND
F. Documentation from the prescriber, patient meets ONE of the following:
    a. Female patient: Alcohol consumption is < 20 grams/day.
    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; OR
    b. Male patient: 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 in combination with appropriate diet and exercise program; 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; 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.