



Commercial PA Criteria

Effective: May 9th, 2024

Prior Authorization: Rezdifra (resmetirom)

Products Affected: Rezdifra (resmetirom) tablets

Medication Description: Resmetirom is a partial agonist of the thyroid hormone receptor-beta (THR- β). 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).

Covered Uses: Noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis

Exclusion Criteria:

1. Metabolic-Dysfunction Associated Steatotic Liver Disease (MASLD)/Non-Alcoholic Fatty Liver Disease (NAFLD)
2. Metabolic-Dysfunction Associated Steatohepatitis (MASH)/Non-Alcoholic Steatohepatitis (NASH) with Cirrhosis.

Required Medical Information:

1. Diagnosis
2. Medical History

Prescriber Restriction: The medication is prescribed by, or in consultation with, an endocrinologist, gastroenterologist, or hepatologist.

Age Restriction: Patient is ≥ 18 years of age

Coverage Duration: 12 months

Other Criteria:

Initial Approval Criteria

1. **Metabolic-Dysfunction Associated Steatohepatitis (MASH)/Non-Alcoholic Steatohepatitis (NASH), with Moderate to Advanced Liver Fibrosis.** Approve if the patient meets the ONE of the following (A or B):
 - A. **Initial Therapy:** Approve if the patient meets ALL of the following (i, ii, iii, iv, v, vi, and vii):
 - i. Patient is ≥ 18 years of age; **AND**
 - ii. Prior to treatment with Rezdifra, the diagnosis of MASH/NASH is confirmed by ONE of the following (a or b):
 - a. Patient has had a liver biopsy AND meets BOTH of the following [(1) and (2)]:
 - (1) Liver biopsy has been performed within the 6 months preceding treatment with Rezdifra; **AND**
 - (2) Liver biopsy shows non-alcoholic fatty liver disease activity score of ≥ 4 with a score of > 1 in ALL of the following ([i], [ii], and [iii]):
 - (i) Steatosis; **AND**
 - (ii) Ballooning; **AND**

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- (iii) Lobular inflammation; **OR**
 - b. Patient has had ONE of the following imaging exams performed within the 3 months preceding treatment with Rezdifra [(1), (2), or (3)]:
 - (1) Elastography; **OR**
Note: Examples of elastography include, but are not imputed to vibration-controlled transient elastography (e.g., FibroScan), transient elastography, magnetic resonance elastography, acoustic radiation force impulse imaging, shear wave elastography.
 - (2) Computed tomography; **OR**
 - (3) Magnetic resonance imaging; **OR**
 - iii. Patient meets ONE of the following prior to treatment with Rezdifra (a or b):
 - a. Patient has stage F2 fibrosis; **OR**
 - b. Patient has stage F3 fibrosis; **AND**
 - iv. According to the prescriber, the patient has THREE or more of the following metabolic risk factors that are managed according to standard of care (a, b, c, d, e):
 - 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**
 - v. According to the prescriber, patient meets ONE of the following (a or b):
 - 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.
 - vi. The medication will be used in combination with appropriate diet and exercise therapy; **AND**
 - vii. The medication is prescribed by or in consultation with an endocrinologist, gastroenterologist, or hepatologist.
- B. Patient is Currently Receiving Rezdifra: Approve if the patient meets ALL of the following (i, ii, iii, iv, v, and vi):
Note: A patient who has received < 1 year of therapy or who is restarting therapy should be considered under Initial Therapy.
- i. Patient meets ONE of the following (a or b):
 - a. Patient has completed ≥ 1 year and < 2 years of therapy with Rezdifra AND patient has derived benefit from treatment with Rezdifra as demonstrated by at least ONE of the following, according to the prescriber [(1) or (2)]:
Note: This applies to a patient starting their second year of therapy with Rezdifra.
 - (1) MASH/NASH resolution AND no worsening of fibrosis; **OR**
 - (2) No worsening of MASH/NASH AND improvement in fibrosis by ≥ 1 stage; **OR**
 - b. Patient has completed ≥ 2 years of therapy with Rezdifra AND according to the prescriber, the patient has not had worsening of fibrosis or MASH/NASH; **AND**
Note: This applies to a patient starting their third year (or more) of therapy with Rezdifra (i.e., the patient has already completed at least 2 years of therapy with Rezdifra).
 - ii. Patient has not progressed to stage F4 (cirrhosis); **AND**
 - iii. According to the prescriber, metabolic risk factors are managed according to standard of care; **AND**
 - iv. According to the prescriber, patient meets ONE of the following (a or b):

- 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.
- iv. The medication will be used in combination with to appropriate diet and exercise therapy; **AND**
- v. The medication is prescribed by or in consultation with an endocrinologist, gastroenterologist, or hepatologist.

References:

1. Rezdifra™ tablets [prescribing information]. West Conshohocken, PA: Madrigal; March 2024.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	05/09/2024