

REZDIFFRA (resmetirom)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Noncirrhotic nonalcoholic steatohepatitis (NASH)

AND ALL of the following:

- a. Moderate to advanced liver fibrosis (stages F2 to F3) as confirmed by **ONE** of the following:
 - i. Liver biopsy, performed within the last 6 months
 - Nonalcoholic Fatty Liver Disease Activity score (NAS) ≥ 4
 OR if NAS <4, hepatocyte ballooning and steatosis are
 present
 - ii. Elastography (e.g., Fibroscan), computed tomography, or magnetic resonance imaging within the last 3 months
- b. Patient has **THREE** or more of the following conditions that are managed according to standard of care:
 - i. Central obesity
 - ii. Hypertriglyceridemia
 - iii. Reduced high-density lipoprotein cholesterol (HDL)
 - iv. Hypertension
 - v. Elevated fasting plasma glucose (i.e., diabetes or pre-diabetes)
- c. Prescribed by, or in consultation with, an endocrinologist, gastroenterologist or hepatologist
- d. Used in conjunction with diet and exercise

AND NONE of the following:

- a. Stage F4 liver fibrosis (cirrhosis)
- b. Significant alcohol consumption (≥ 2 alcoholic drinks per day) for a duration of more than 3 months in the last year
- c. Diagnosis of hepatocellular carcinoma (HCC)
- d. Chronic liver diseases (e.g., primary biliary cholangitis, primary sclerosing cholangitis, Hepatitis B positive, Active Hepatitis C, etc.)



REZDIFFRA (resmetirom)

Prior - Approval Limits

Quantity 100 mg per day

Duration 12 months

Prior - Approval Renewal Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Noncirrhotic nonalcoholic steatohepatitis (NASH)

AND ALL of the following:

- a. Improvement in fibrosis by at least 1 stage within 1 year of treatment **OR** patient has had no worsening of fibrosis after 2 years or more of therapy
- b. Patient has not progressed to stage F4 (cirrhosis)
- c. Metabolic risks are managed to standard of care
- d. Used in conjunction with diet and exercise

AND NONE of the following:

- a. Significant alcohol consumption (≥ 2 alcoholic drinks per day) for a duration of more than 3 months in the last year
- b. Diagnosis of hepatocellular carcinoma (HCC)
- c. Chronic liver diseases (e.g., primary biliary cholangitis, primary sclerosing cholangitis, Hepatitis B positive, Active Hepatitis C, etc.)

Prior - Approval Renewal Limits

Same as above