Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	September 19, 2024

Rezdiffra™ (resmetirom)

LENGTH OF AUTHORIZATION: Up to 1 year

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age.
- Patient must have a documented diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis, consistent with stages F2 to F3 confirmed by at least one of the following *(official diagnostic testing results must be provided):*
  - Liver biopsy performed within the past 6 months with a NAFLD Activity Score (NAS) ≥ 4;
  - Enhanced liver fibrosis (ELF) panel;
  - Fibrosis Index Based on 4 Factors (FIB-4);
  - Vibration-controlled transient elastography (VCTE) (e.g., FibroScan).
- Patient **does not** have any of the following:
  - Cirrhosis;
  - Liver decompensation;
  - Moderate to severe hepatic impairment (Child-Pugh Class B or C).
- Medication will be taken in conjunction with a low-fat diet and exercise.
- Medication was prescribed by, or in consultation with a hepatologist, gastroenterologist or specialist in the area of the patient's diagnosis.

CONTINUATION OF THERAPY:

- Patient met initial review criteria; **AND**
- Documentation of improved clinical response (e.g., NASH resolution or improvement in liver fibrosis); **AND**
- Patient has not experienced any treatment-restricting side effects (e.g., Acute cholecystitis, cholelithiasis or hepatotoxicity); **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 60 mg, 80 mg, and 100 mg tablets.